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Overview of data and methodologies and data gap identification in exposure assessment for PPPs in residential settings

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Abstract

Since a harmonized approach for the risk assessment of non-professional/home garden plant protection products (PPPs) has not yet been agreed, substantial differences exist between EU Member States (MS). The multidisciplinarity and the specificity of the topic, in one hand related to PPPs but also to biocide products (BPs), has been addressed by a consortium with the appropriate expertise in the related fields. In this context, the present project characterized exposure scenarios and determinants for non-professional use of PPPs and gathered all relevant available methodologies and approaches to address non-dietary exposure assessment. Data and methodologies were evaluated for their adequacy and data gaps were identified to assess the exposure in indoor and greenhouse locations. To address identified data gaps and to characterize the generic use (outdoor and indoor) of non-professional PPP, surveys targeted to non-professional users were conducted in Italy and the Netherlands. Additionally, a survey among competent authorities was conducted to provide an overview on the rules, methodologies, basic default values adopted by EU Member States in the authorization process. Overall, the results of this project provided valuable information to address risk assessment of non-professional use

of PPPs, identified data gaps for exposure assessment that require further work and areas that require harmonization.

Key words: non-professional use, non-dietary exposure, plant protection products, risk assessment

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Summary

The risk associated to the non-dietary exposure to plant protection products (PPPs) was historically focused on their professional use. More recently attention is increasingly paid on the risk associated to the non-professional use of PPPs, in residential settings. However, there is no agreed and harmonized approach to assess the relevant non-dietary exposure.

This project aimed at collecting all relevant information in preparation of the knowledge grounds for future risk assessment challenges. The multidisciplinarity of the matter required the establishment of a consortium with extensive experience in the field of exposure and risk assessment of PPPs but also of biocidal products (BPs), since in several cases exposure scenarios in place for BPs used by the general public may be relevant.

This exercise required to identify, characterize, and analyse exposure scenarios, exposed individuals, and parameters/factors in residential settings (outdoor, greenhouse and indoor). Consequently, existing and new data, and methodologies for non-professional non-dietary exposure assessment were collected and evaluated for their adequacy for regulatory purposes. Two targeted surveys were conducted in Italy and The Netherlands. Additionally, a survey was conducted among EU Member States (MSs) competent authorities to retrieve information regarding the authorization rules, the hazard-based restrictions set, and the approaches/tools used by the different EU MSs. This questionnaire was aimed also at the identification of the needs and gaps, as realized by regulators and risk managers among the three EU zones.

The outcome of the project activities indicated that there is a reasonable number of models and approaches available to assess exposure to PPPs in residential outdoor settings, covering a range of product types, formulations, applications, targets, tasks, and default values. Therefore, no substantial data gaps were identified for the outdoor location.

For the indoor location, other than greenhouse use, available data and methodologies are adequate for assessing the exposure of the user, however, data gaps were identified for those exposure determinants relevant to assess indirect post-application exposure, i.e. residents' exposure.

For the greenhouse residential scenario, although no specific model was identified, the tools used for the PPPs for professional use may be considered, assuming a reduced surface area. Exposure for users during mixing, loading, application and re-entry activities should be considered, while bystanders are considered unlikely to be present during application.

Results from the survey conducted in Italy, showed that insecticides and herbicides are most frequently used in vegetable and ornamental gardens. Regarding the types of products, ready-to-use (RTU) liquids or liquids concentrate that require dilution are preferred compared to solids RTU or solids that require dilution. The preferred equipment used for application are RTU nebulizer sprayers, followed by backpack pressurized dispenser with lance, pressurized dispenser with launce (approx. 3 to 6 litres) and spray can, hand pressurized spray (spray dilution to be prepared) and nebulizer (spray dilution to be prepared). The amounts of PPPs applied are generally small, requiring less than 5 minutes of application, except for orchards where the majority indicated to spend from 5 to 30 minutes. In all locations most respondents indicated a seasonal or monthly use. Only few records were reported for a daily use (ornamentals and vegetable garden). About half

of the respondents indicated to apply PPPs on both small and high potted plants located indoors, and a small portion of participants (6%) has a greenhouse with a size less than 15 m^2 with ventilation. In general, non-professional users are aware of managing PPPs and handle the product with gloves, as well as keeping people and pets away from the areas where the PPP is applied.

Similar observations were seen in the survey conducted with a consumer panel in the Netherlands. Weed killers, slimicides, insecticides and treatment against moss, algae, fungi on pavement are mostly used in the garden. Insecticides, treatment against moss, algae, fungi on pavement and lawn treatment product are also used indoors. Most non-professional users apply PPPs during growth season with at least weekly use with a preference for RTU products, followed by concentrate that needs to be diluted. The amounts of either RTU or concentrated products, against moss, algae and fungi and lawn treatment are generally greater than for other pesticides. More than half of participants have small to medium or large plants in the home and/or balcony. Half of the users reported wearing no protective equipment while using PPPs and only a quarter of respondents using lawn treatment products reported wearing a respiratory mask. Few participants have a greenhouse, among these, the majority indicated a size ranging from 1 to 15 m^2 with ventilation.

All Member State competent authorities apply hazard-based restrictions for the authorization of non-professional PPPs. For exposure estimation, most MSs apply the UK POEM (amateur/home garden), the German model (home and allotment garden area) and the EFSA calculator. Other approaches/models used in other regulatory frameworks, e.g., in biocides, are also considered. For exposure variables such as maximum task duration, most MSs consider 2 hours. RTU sprayers and spray cans are the most relevant application equipment for non-professional use. The German Guidance is considered rather obsolete by the majority of MSs for bystander/resident exposure assessment, with the EFSA Guidance being used instead. Little can be deduced with respect to the type of greenhouse considered for non-professional assessment. Some MSs assess the indoor uses in the same manner as they do for the outdoor ones. The use of personal protective equipment (PPE) for refining the exposure assessment is not accepted by the majority of MSs and setting a re-entry period as a risk mitigation measure is not considered acceptable.

Overall, the results of the present work outlined the available information to address risk assessment for exposure to non-professional use of PPPs and identified the need of a standardized and harmonized approach accounting for regional differences, where relevant. Data gaps were identified for certain exposure determinants pertaining the use of PPPs in indoors and greenhouses, such as the surface area of plants, drift values and contact area. Although the identified data gaps could not be completely covered by the survey conducted, the collected information/data could be the grounds for reconsidering or changing the already existing defaults. Further work is envisaged to fill the identified data gaps and workshops are recommended to determine the preferred models or approaches for specific products.

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1 Introduction

In assessing the potential health risks associated with exposure to pesticides, attention has historically been focused on dietary exposure to residue and professional exposure of operators and workers. In the last years also bystander and resident exposure assessment became a mandatory requirement in authorization/registration process.

In the current years, several non-dietary exposure assessment methodologies have been agreed and international agencies/authorities guidelines have been delivered on professional exposure scenarios.

In this context, attention should also be paid to the use of pesticides by non-professional users (e.g., in private gardens and indoor use), where appropriate rules need to be adopted to minimize the risks. Most countries apply cut-off criteria based on the hazardous properties of the products when considering non-professional users, as these criteria respond to the need to restrict the access of some pesticides to those users and to remove the most toxic substances from the non-professional market. However, even if these cut-off criteria greatly limit the availability of many substances that should not be in the hands of non-professionals, there are still products on the market that may be of concern to public health, in particular for children and babies (as by-standers or through secondary exposure), and under this view additional assessments are needed.

According to Directive 2009/128/EC: *"Sales of pesticides, including Internet sales, are an important element in the distribution chain, where specific advice on safety instructions for human health and the environment should be given to the end user at the time of sale, in particular to professional users. For non-professional users who in general do not have the same level of education and training, recommendations should be given, in particular on safe handling and storage of pesticides as well as on disposal of the packaging."*

In some European countries (such as Sweden and Italy) training is required for distributors/retailers selling both professional and non-professional use pesticides and all premises selling pesticides must have a trained person available to provide information on safe pesticide use.

In other countries, the ban on the sale of pesticides, except for Ready-To-Use products, *via* user instruction labels helps to ensure that amateur users receive instructions on the safe use of pesticides at the time of sale.

In the majority of Member States (MS) awareness-raising campaigns to inform the general public and non-professional users about the hazards and risks associated with the use of pesticides have been carried out.

In the European regulation on active substance authorization and placement on the market the following is stated: *A significant difference in risk shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific*

vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account.

Even if some exposure scenarios and the corresponding determinants can be adopted from the exposure scenario for professional use, the residential behaviour and practice of non-professional users are unique to non-professional uses, that seems to be more similar to biocide products (BPs) exposure scenarios. This highlights the need for specific risk assessment and management options. Thus, different assumptions are currently made by either regulatory authorities or manufacturers on non-professional users.

1.1 Background and terms of reference as provided by the requestor

This project was awarded by EFSA to: University of Milan (UNIMI), Department of Biomedical and Clinical Sciences, Italy - National Institute for Public Health and the Environment (RIVM), the Netherlands - Benaki Phytopathological Institute (BPI), Greece.

Coordinator / Project Leader: University of Milan

Grant title: Capacity building and knowledge transfer in non-dietary exposure assessment to non-professional use of PPPs.

Grant number: GP/EFSA/ENCO/2020/03

1.2 Purpose

Since no harmonised approach for the risk assessment of non-professional/home garden products has yet been agreed, substantial differences exist between EU MS. Exposure assessments are very much based on case-by-case decisions utilizing different approaches. This is also due to the lack of specific data.

The non-professional scenario needs an exposure assessment characterised by specific exposure determinants (parameters that describe exposure) to be considered reliable and accounting for cultural, territorial and climate differences between European countries. Any newly gathered data and developed methodology should be able to accommodate those differences, while still maintaining a high level of harmonisation within the assessment of the non-professional exposure to PPPs across the different uses within MS.

This project was aimed at preparing and implementing the knowledge grounds for future risk assessment challenges in non-dietary risk assessments for non-professional use of PPPs. The objective was pursued by defining and updating information related to different non-professional behaviour practices, application techniques, generating, collecting, collating, synthesising and analysing evidence from exposure parameters data. This was

possible through the transfer and exchange of knowledge among institutions with extensive experience in the field of PPPs exposure and risk assessment and development of related methodologies, including biocides.

2 Data and Methodologies

2.1 Data

The conceptual and practical framework of the present project is illustrated in Figure 1. Before collecting information for non-dietary risk assessments for non-professional use of PPPs exposure scenarios and characterisation of all relevant exposure determinants (parameters and factors in residential outdoor and indoor settings) in residential settings were identified. Thereafter, existing data and exposure methodologies for PPPs exposure assessment in residential settings were retrieved and collected. Furthermore, data, approaches and methodologies relevant for PPPs exposure assessment from biocide framework were collected and described. A data gap analysis was then conducted comparing completeness and adequacy of the retrieved information against the previously identified exposure scenario and exposure determinants, considering locations of use (outdoor, greenhouse and indoor) and exposed actors (user, user re-entry, resident and bystander). In an attempt to cover the identified data gaps, an open literature search analysis was performed. Additionally, the results of the data gap analysis were the basis to outline the surveys. Beyond trying to fill the identified data gaps the surveys were also implemented to characterise the generic use of the PPP by non-professionals in indoor and outdoor (around the house) locations in at least two countries, *i.e.,* Italy and The Netherlands.

Furthermore, the relevant information retrieved in the literature search and the "non-professional user" survey pilot results were also used as the basis for the development of a "branch organizations and authorities" questionnaire, aimed to be shared within the EU competent authorities to collect information on the approaches and methodologies applied by the different MSs.

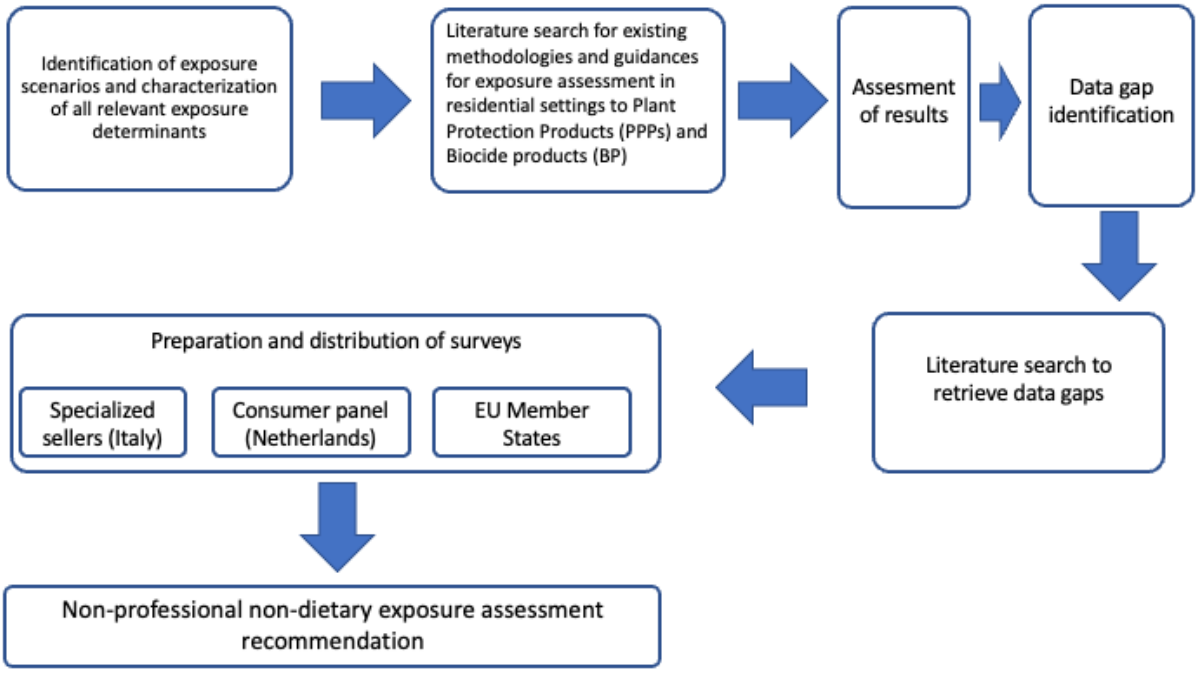


Figure 1: Project conceptual and practical framework

2.2 Methodologies

2.2.1 Exposure scenarios / determinants

Exposure scenarios and relevant exposure determinants for non-professional use of plant protection products (PPPs) were identified taking into consideration types of pesticide products (e.g. herbicides, fungicides), formulations (e.g. solids, liquids), product types (e.g., ready to use), application equipment (e.g. trigger sprayer, pump sprayers), application locations (e.g. outdoor, indoor), route of exposure (e.g. dermal, inhalation), type of exposure (direct, indirect) and actors potentially exposed to the PPPs among non-professional products (e.g. user, user re-entry, resident and bystander) authorised in Italy, Greece and the Netherlands. Consequently, the non-dietary exposure assessment for non-professional use of PPPPs was compared to the approach used in the context of professional uses of PPPs and to the approach for biocides for similarities.

2.2.2 Existing data, exposure methodologies and guidances for PPPs exposure assessment in residential setting

A review of the available scientific and grey literature data on the exposure of non-professional users of PPPs and the exposure assessment related to the non-professional use of PPPs for all relevant populations was conducted.

2.2.3 Open literature search - data/methodologies relevant for non-professional use of pesticides

Complementary to the review of the existing methodologies used, an open literature search has been conducted in order to retrieve any publicly available exposure data/methodologies relevant to non-professional use of pesticides. Different search strings have been considered for searching the open literature (SCOPUS) before concluding on the ones to be finally used. While including terms such as "operator", "worker", or "farmer" in combination with "pesticide" or "plant protection product" in the search string resulted in a very high number of references, the search outcome was limited when considering in addition the terms "amateur" or "non-professional" and "exposure".

2.2.4 Existing data and exposure methodologies for BPs exposure assessment in residential settings

Exposure methodologies applied in the framework of biocides were sought through for their relevance for the prediction of PPP in residential settings. The existing data and approaches were collected and described. First an overview of relevant methodologies for PPPs exposure assessment were selected from the Biocides methodology document, the Ad hoc Working Group – Human Exposure recommendations and previous HEEG opinions and the ConsExpo fact sheets with the Pest Control Products Fact Sheet (Bremmer *et al*., 2006) and Disinfectant Products Fact Sheet (Prud'homme de Lodder *et al*., 2006). Next a list of PPPs that have been authorised for non-professional use in the Netherlands was requested from the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb). In a following step, the PPPs were categorised by application method and suggestions are given on available models from biocides to estimate the exposure of non-professional use in the residential settings (outdoor, indoor and greenhouse).

2.2.5 Open literature search for indoor scenario data gaps

Open literature search has been conducted with SCOPUS database. Different search strings have been considered for searching the relevant literature related to the data gap identified for the indoor non-professional use of PPPs (see section 3.5.3):

1) Terms "drift" or "deposit", and "indoor" in combination with "pesticide" or "plant protection product" in the search string resulted in a high number of references; the search outcome was limited when considering in addition the terms "amateur" or "non-professional".

2) Terms "area treated" or "plant pot" and "indoor" or "house" in the search string resulted in a high number of references that however are mainly out of topic.

3) Terms "dimension" or "ventilation" and "glasshouse" or "greenhouse" and "amateur" or "non-professional" in the search string resulted in a limited number of references that are mainly out of topic.

2.2.6 Surveys

2.2.6.1 "NON-PROFESSIONAL USER SURVEY"

The questionnaires delivered to non-professional users of PPPs were implemented to characterise and identify the types of application and packaging, such as ready to use (RTU) packs and those products, which require some measurement, and mixing prior to use. In an effort of valorisation of all available data and information, a draft questionnaire was structured taking into account relevant information retrieved in the literature and the already available reports such as the guidance documents for the zonal assessment of PPPs and EFSA funded projects (CT/EFSA/PPR/2010/04 and CTF/EFSA/PPR/2010/) carried out in EU Member States to address cumulative exposure to plant protection products. Additional publications about collection of pesticide application data were also taken into consideration.

The scenario of non-professional use of PPP is characterized by the peculiarity of having features in common with the use of PPPs and biocidal products. For this reason, the transfer and sharing of knowledge between partners with expertise in plant protection products and biocides exposure characterization and assessment was a fundamental prerequisite for the development of the questionnaires.

A "non-professional user" questionnaire proposal was prepared and shared among partners describing the initial set of questions, the target samples, the expected sample size, how data was elicited (ad hoc designed questionnaire), how subjects will be contacted and interviewed, and estimated lengths of interview/questionnaire compilation. The consortium worked closely in drafting the questionnaires focusing on adequacy and completeness of questions as well as on the best strategy to increase their clarity.

The questions dealt with topics about the use of PPPs and residential settings including gardens and greenhouses. The survey included the following five product groups: weed killers, slimicides, insecticides against lice, moth and other pests, products against moss, algae and fungi, and lawn treatment.

The possible answers to questions were harmonised as well, where the granularity of response for some questions was higher in the Netherlands than in Italy. However, the granularity in responses were set in such a way that by pooling answers the results were again comparable between the surveys. Where possible, similar pictures to support the

responder in the survey to understand better the question were used. Further, it may be that typical examples of a product are different in the Netherlands compared to Italy. For questions regarding the amount and type of plotted plants indoors the same pictures were used in the Dutch and Italian questionnaires for complete comparability. Overall, a tight collaboration between partners was aimed at harmonizing all questionnaires sections.

RIVM and UMIL have adopted different methodologies for screening the non-professional PPPs users. RIVM contacted consumers in the Netherlands directly through a marketing panel *via* a survey. The conducting of the survey was subcontracted to Motivaction by RIVM. UMIL made use of Lombardy agricultural seller cooperation for the survey distribution, which is constituted of about 400 PPP retails.

Specialised sellers (UNIMI - Italy)

The targets of the questionnaire were specialised seller's clients. Given that promotion and delivery of the survey by the sellers was on voluntary basis, regulatory body (Welfare Directorate of Lombardy Region), national sector association of sellers (National Association of Agricultural Sellers) and three large agricultural consortia located in Lombardy, Emilia Romagna and Veneto regions were involved ahead of schedule to maximise the number of survey respondents. Since the target of the survey were non-professional users of PPPs not specifically selected for responding to the survey, the questionnaire was meant to be as simplest as possible with a reasonable low number of questions and multiple-choice answers.

A definitive version of the questionnaire has been implemented and finalised taking into consideration the results of the pilot questionnaire and the feedback from EFSA and partners regarding alinement between the surveys of UNIMI and RIVM.

- ✓ The survey, together with an information leaflet, was delivered to 400 PPP retails located in the region of Lombardy. This delivery was preceded by a preview information letter. The questionnaire was provided in paper and digital format, this latter via a QR-Code.
- ✓ Several e-mails and some direct phone calls were made for supervising the receipt of the material and the progress of the survey.
- ✓ Sellers were also asked to send us by e-mail scanned paper completed questionnaires on a voluntary basis.

The survey lasted from April 2022 to January 2023. At the beginning, only 10% of the involved 400 PPP retails actively participated and promoted the survey. This can be explained by the fact that PPP sellers are currently not able to allocate sufficient time/staff to promote/divulgate the survey due to high seasonal workload.

Moreover, the constant monitoring of the progress of the contribution over the months, allowed us to understand how difficult it is to sensibilise non-professional users on the safe use of PPPs.

Detailed questionnaire used in the survey can be found in Appendix B.

Consumer panel (RIVM – Netherlands)

Since the survey in the Netherlands targeted non-professional users of PPPs, selection questions were asked to the panel that was included in the survey. The panel is constructed by random stratified selection of persons in the Netherlands. This means that panel members are coming from different regions of the country, different age groups, and backgrounds. Overall, the aim has been to have a representative panel for the adult Dutch population consisting of a minimum 500 responders that may include users and non-users.

Exclusion criteria were targeted to eliminate responders that do not run their own household to get to the target population. For example, students living in dorms or adults still living with their parents. It was considered that they are not typical users of such products in their household. The next exclusion criterion was whether or not the responders use a registered PPP. Since people may not be aware that a specific product is registered as PPP, it was explained by asking: is the product purposely marketed to protect plants, gardens, lawn or terraces against pests? This question has been considered to exclude products like vinegar, salt or hot water; thus, the group that has been excluded can be considered as non-users of registered PPPs. The responders that responded 'I do not know' to that particular question have also been included within the non-users. This excluded group did not fill in the remainder of the survey. The remaining group is a user of at least one PPP in a residential setting.

Detailed questionnaire used in the survey can be found in Appendix C.

2.2.6.2 "AUTHORITY SURVEYS"

The "branch organisations and authorities" questionnaire has been structured taking into account both the relevant information retrieved in the literature search and the already available reports such as the guidance documents for the zonal assessment of PPPs. The pilot "non-professional user" survey results have also been considered.

The questionnaire, as finalised following consultation with EFSA, is presented in Appendix D. An effort was made on one hand to include targeted questions in the form of "*multiple choice*", to facilitate the analysis of the responses, but also to provide the responders the possibility to include any information required for addressing adequately each question.

The questionnaire was shared with the Member States through the Post Approval Issues Working Group and the Interzonal Steering Committee (PAI WG/IzSC) on the 5th of December 2022. Member States were asked to provide their feedback by the 13th of January 2023.

The fact that the questionnaire has been shared through a specific channel to MS facilitated the direct contact in case any clarification was required.

In total fourteen (14) authorities have participated in the survey:

EU Member State	Organisation/Authority
Austria	AGES - Austrian Agence for Health and Food Safety
Belgium	Federal Public Service Health, Food Chain Safety and Environment / Service Plant protection and Fertilising Products
Denmark	Danish environmental protection agency
Finland	Finnish Safety and Chemicals Agency
Germany	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)*
Greece	Benaki Phytopathological Institute (BPI)
Ireland	Pesticide Registration and Controls Division, Department of Agriculture Food and the Marine
Italy	Ministry of Health
Lithuania	The State Plant Service under the Ministry of Agriculture
Netherlands	Dutch Board for the Authorisation of Plant Protection Products and Biocides - Ctgb
Norway	Norwegian Food Safety Authority; National Approvals Department
Slovenia	The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection
Spain	Ministry of Health**
Sweden	Swedish Chemical Agency (Kemikalieinspektionen)

* BVL is responsible for risk management and authorisation of PPP; the answers have been provided by BVL on the basis of the replies of the competent authorities for the risk assessment:
  - Bundesinstitut für Risikobewertung (BfR) - Toxicology, Residues and respective analytical methods
  - Umweltbundesamt (UBA) - Environmental Fate and behaviour, Ecotoxicology
  - Julius Kühn-Institut - Bundesforschungsinstitut für Kulturpflanzen (JKI) - Efficacy, Honey bees
  - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) - Identity, Phys. chem. properties and respective analytical methods.

** Responses elaborated in collaboration with National Institute Occupational Safety and Health.

3 Results

3.1 Exposure scenarios

Similar to the risk assessment for professional use of PPPs, the same categories of individuals are exposed (operator, bystander, resident and worker) and the same types of exposure (direct or indirect) and exposure routes (dermal and/or inhalation) are identified for the non-dietary risk assessment for non-professional use of PPPs (Charistou *et al.*, 2022). The non-dietary exposure and the risk assessment for non-professionals should be carried out without considering the use of personal protective equipment, preventive measures and limitation of uses.

Exposure estimates for professional uses of PPPs are carried out assuming that activities of mixing & loading and application, and re-entry activities (e.g.: inspection, irrigation and harvesting) are conducted by different actors. In contrast, considering the reduced surface areas and duration of tasks of non-professional uses of PPPs, it is plausible to consider that the same person would prepare the product (if not ready to use), apply it and would get in contact with treated crops following re-entry activities. In addition, the user is also a resident and is exposed also post application where a distinction in direct (residues on plants) and indirect (off target residues) exposure should be considered. Consequently, it is acknowledged that finally the estimated exposure resulting from mixing & loading, application and post application activities should be summed up.

Exposure estimation during the application (direct) and after application (indirect) depends mainly on the type of application (equipment used), the application target (crop type: high/low) and the amount applied. Other parameters that can affect specially the exposure of non-professional users (during mixing & loading, are the type (physical state) of formulation and the type of containers.

The following scenarios are considered for different application locations: outdoor, indoor (plants in pots in house) and greenhouse.

3.1.1 Outdoor

This scenario is divided into sub-scenarios on the basis of following crop categories:

1. Field crops (< 50 cm), such as zucchini and beans;
2. Tree early, ≤ 2 m (ornamental/fruit);
3. Tree late (ornamental/fruit), e.g., pome fruits and grapevines;
4. Tree early, > 2 m (ornamental/fruit), e.g., spring pome fruits;
5. Vegetables, cereals, berry fruit and ornamentals (> 50 cm), e.g., strawberries;
6. Lawn.

The exposure assessment for these scenarios is carried on considering three types of actors (user, bystander and resident) in different exposure scenarios:

USER (ADULT)

Exposed during:

- Mixing & loading of products (v*ia dermal and inhalation*);
  For ready to use products (RTU), water-soluble bags, tablet or sticks the exposure is considered negligible;
- Application (v*ia dermal-spray and inhalation-spray*);
- Post application (direct) activities (*via dermal*).

BYSTANDER (ADULT AND CHILD)

Exposed during:

- Application (*via dermal-spray and inhalation-spray*).
- Post application (direct)
  - Accidental entry into treated crops/plants adult and child (*via dermal and inhalation – exposure to vapour*).

RESIDENT (ADULT AND CHILD)

Exposed during:

- Post application (indirect)
  - Adult (*via dermal and inhalation-vapour*);
  - Child (*via dermal, inhalation-vapour, orally hand to mouth, orally object to mouth*).
- Post application (direct)
  - Accidental entry into treated crops/plants adult (*via dermal)* and child (*via dermal and oral*).

3.1.2 Indoor

Although the non-dietary exposure risk assessment approach for professional use of PPPs does not contemplate the application indoors, it can be applied also for indoor use for what concerns the categories of individuals exposed (operator, bystander, resident and worker), exposure (direct or indirect), exposure routes (dermal and/or inhalation). For the indoor location, no crop typology differences are considered. In indoor use, the exposure of the user during mixing & loading of the products depends on the type (physical state) of formulation, the type of containers (size and shape), and amount required, while the amount of product applied is the main driver of the user's exposure during application, and the bystander and resident exposure. For bystanders indoor, the exposure resulting from accidental entry into treated crops (post application) has not been taken into consideration as it is considered to be covered by the resident.

The following types of actors are considered in the exposure assessment in indoor locations:

USER (ADULT)
Exposed during:

- Mixing & loading of products (v*ia dermal and inhalation*);
  For ready to use products (RTU), water-soluble bags or tablets the exposure is considered negligible;
- Application (v*ia dermal-spray and inhalation-spray*);
- Post application (direct) activities (v*ia dermal*).

BYSTANDER (ADULT AND CHILD)
Exposed during:

- Application (v*ia dermal-spray and inhalation-spray*).

RESIDENT (ADULT AND CHILD)
Exposed during:

- Post application (indirect)
  - Adult (*via dermal and inhalation-vapour*);
  - Child (*via dermal, inhalation-vapour, orally hand to mouth, orally object to mouth*).
- Post application (direct)
  - Accidental entry into treated crops/plants adult (*via dermal)* and child (*via dermal and oral*).

3.1.3 Greenhouse

This scenario does not account for the different typologies of crops. The exposure of the user during mixing & loading (if needed) is determined by the formulation type and by the package, while the amount of applied product affects the user during the application phase.

For the greenhouse scenario the exposure is estimated for the user during mixing & loading (if needed), the application and re-entry activities. Bystanders are unlikely to be present during application, residents (adult and child) exposure should be considered as for the indoor scenario accounting however probably only for the entry into treated crops.

USER (ADULT)
Exposed during:

- Mixing & loading of products (v*ia dermal and inhalation*);
  For ready to use products (RTU), water-soluble bags or tablets the exposure is considered negligible;
- Application (v*ia dermal-spray and inhalation-spray*);
- Post application (direct) activities (*via dermal and inhalation - vapour*).

RESIDENT (ADULT AND CHILD)

Exposed during:

- Post application (direct);
- Accidental entry into treated crops/plants adult (via dermal) and child (via dermal and oral).

3.2 Relevant exposure determinants

3.2.1 Outdoor

For the outdoor location(s) a number of exposure determinants can be derived from professional PPP or biocide use exposure scenarios. The following parameters describe and characterise the specific scenario of non-professional plant protection products application in outdoor environment differentiated by the above-described sub–scenarios.

GARDEN AND VEGETABLE GARDEN

User

1. Application method: handheld, low and high level target
   - Formulation type: liquid or solid;
   - Container size/measuring of concentrate solution: exposure determinants during M&L;
   - Tank size;
   - Exposure values for dermal and inhalation during application;
   - PPE: only normal non-professional clothing;
   - Treated area;
   - Application duration.

2. Application method: ready to use products
   - PPE: only normal non-professional clothing;
   - Exposure durations
   - Exposure values for dermal and inhalation

Resident/bystander (post application, indirect)

- Drift values
- Vapour concentration (mg/m^3): semi-volatile or volatile;
- Dermal and inhalation (bystanders: vapour; resident: spray) exposure time;
- Turf Transferable Residue (TTR)÷
- Inhalation volume: adult and child;
- Saliva extraction factor;
- Surface area of hands;
- Frequency of hand-to-mouth;
- Dislodgeable foliar residue (DFR)(oral exposure);
- Dislodgeable foliar residue (DFR)(dermal exposure);
- Ingestion rate for mouthing of grass/day;

Post application (direct)

User

- Dislodgeable foliar residue (DFR);
- Transfer coefficient (TC);
- Re-entry time for inspection, crop maintenance, harvesting and irrigation;

Resident/bystander: accidental entry into treated crops/plants (adult, child)

- Dislodgeable foliar residue (DFR);
- Transfer coefficient (TC);
- Re-entry duration.

LAWNS

Lawn scenario could be considered similar to garden/vegetable garden scenario except for the fact the treated area and consequently, exposure time are expected to be greater.

- Treated area;
- Application duration;
- Drift value.

For this scenario, re-entry exposure should not be considered for child and adult as it could be considered to be covered by resident (child and adult) exposure, as the resident is supposed to be exposed in activities in lawns, as assessed in the resident lawn scenario.

3.2.2 Indoor

Differently than the outdoor location extrapolation of exposure assessment approach and determinants from professional use of PPP is less obvious, instead the exposure assessment approach for indoor biocide products appears to be more similar. Below the exposure parameters/determinants for the indoor scenario:

- Product type: liquid concentrate or solid, or ready to use;
- Application equipment:
  - For liquid concentrate
  - Ready to use

User

- PPE: non-professional usual clothing;
- Exposure values for dermal and inhalation for trigger and aerosol sprays;
- Applied dose (duration of spraying)
  Treated volume/area

Resident/bystander

- Exposure time:
  Resident
  a. Dermal adult and child;
  b. Inhalation-vapour adult and child;
  Bystander
  Inhalation-spray (as for user);
- Transferable residue from different indoor surfaces*;*
- Treated volume/surface;
- Drift values for non-professional PPPs used indoor;
- Vapour pressure (as for the outdoor);
- Breathing rate for adult and child;
- Oral absorption: supposed to be 100%;
- Fraction saliva extraction;
- Fraction of hand mouthed;
- Frequency of hand-to-mouth contacts events per hour;
- Object surface area mouthed*;*
- Number of object-to-mouth contacts events per hour.

3.3 Existing data and exposure methodologies for PPPs exposure assessment in residential settings

Currently, no harmonised approach is available for the non-dietary exposure assessment of non-professional/residential and home garden uses of plant protection products (PPPs). Thus, the exposure assessment conducted is mostly based on case-by-case decisions, while the different approaches/models applied by EU Member States (MSs) may lead to substantial differences. The exposure assessment tools that currently are available and used at national level, are presented below briefly:

3.3.1 Models to assess USER exposure

UK predictive exposure model (UK POEM) Amateur/home garden user exposure models *(for space sprays, surface sprays and dustable powder applications)* – Ready -to -use products (aerosol, trigger sprayers and puffed packs)

The basis of this model are data generated by the UK Health and Safety Laboratory (HSL) in 2001 and considered by the ACP (SC 11000). Consumer exposure to non-agricultural pesticides). These data, related to ready-to-use products, have been considered during the development of the Technical Notes for Guidance by the European Chemicals Bureau (TNsG / TNSG on Human Exposure / Report 2002, Part 2, pages 194 to 197).

The model, in the format of an excel file available in the UK Health Safety Executive (HSE) website [*Amateur/home garden user exposure models (for space sprays, surface sprays and dustable powder applications;* https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/amateur-use-model.xls], provides the user with the possibility to directly estimate the exposure for the scenarios covered introducing only limited information as input. Dermal exposure is expressed as mg/min of ready-to-use product, while the dermal deposition rates relate to actual dermal exposure. Inhalation exposure is expressed as mg/m^3 of ready-to-use product. The nominal density of the product is assumed to be 1.0 g/ml.

More specifically, the following application scenarios are covered by the HSE model:

- AEROSOL SPACE TREATMENT MODEL (Spraying - air space spraying Model 1, TNsG)
  Surrogate values for dermal and inhalation exposure (75th % value, ml/min)

  - Dermal hand and forearm: 0.156 ml/min
  - Dermal leg/feet/face: 0.113 ml/min
  - Inhalation: 0.0039 ml/min

  Exposure duration: 144 sec (2.4 min)

- AEROSOL SURFACE TREATMENT MODEL (Consumer product spraying and dusting Model 2, TNsG)
  Surrogate values for dermal and inhalation exposure (75th % value, ml/min)

  - Dermal hand and forearm: 0.0647 ml/min
  - Dermal leg/feet/face: 0.0357 ml/min
  - Inhalation: 0.0006 ml/min

  Exposure duration: 300 sec (5 min)

- TRIGGER SPRAY SURFACE TREATMENT MODEL (Consumer product spraying and dusting Model 2, TNsG)
  Surrogate values for dermal and inhalation exposure (75th % value, ml/min)

  - Dermal hand and forearm: 0.0361 ml/min
  - Dermal leg/feet/face: 0.0097 ml/min
  - Inhalation: 0.0002 ml/min

  Exposure duration: 30 min

- DUSTABLE POWDERS – PUFFER PACK MODEL (Consumer product spraying and dusting Model 2, TNsG)
  Surrogate values for dermal and inhalation exposure (75th % value, ml/min)

  - Dermal hand and forearm: 2.83 mg/min
  - Dermal leg/feet/face: 2.15 mg/min
  - Inhalation: 0.0296 mg/min

  Exposure duration: 30 min

UK predictive user exposure model (UK POEM) *- [Home garden sprayer (5 litre tank). Outdoor low-level target] – Spray application (hand-held sprayer)*

This UK model, included in the UK POEM tool (excel file) along with the models for the estimation of exposure of professional operators, has been based on studies conducted by DEFRA, i.e.

Development and study of methods for assessing worker and environmental exposure to pesticides(http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=9499#Description),

and

Potential dermal exposure during mixing and loading of amateur pesticides for use in gardens in the UK
(http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&Completed=0&ProjectID=13882#Description).

Based on the aforementioned studies, a specific exposure model for amateur users has been produced, where an application with a 5-litre hand-held sprayer is considered. The model "Home Garden sprayer (5 litre tank. Outdoor, low level target" is available in the format of an excel file [*https://english.ctgb.nl/binaries/ctgb-en/documents/assessment-framework-ppp/2016/10/27/calculation-model-operator-uk-poem/guidance+operator+uk+poem+v01.xls*].

The following cases are covered by the model depending on whether the formulation is a liquid or a solid concentrate:

- LIQUID CONCENTRATE FORMULATIONS

Depending on the way the decanting of the concentrate is performed, three (3) cases have been identified:

- Home garden, in-cap measure: 1 ml of formulation per pouring operation
- Home garden, separate measure: 0.1 ml of formulation per pouring operation
- Home garden integral squeeze-to-fill measuring chamber: 0.01 ml of formulation per pouring operation

For the application phase the following are considered:

- Volume surface contamination: 50 ml/h (same as for professional use)
- Inhalation exposure: 0.02 ml/h (same as for professional use)
- Work rate: 0.01 ha/day
- Duration of spraying: 0.5 h

- SOLID CONCENTRATE FORMULATIONS

For the mixing/loading the following is considered:

- Hand contamination/kg a.s.: 171.4 mg/kg a.s. (data from the German model)

For the application phase the following are considered:

- Volume surface contamination: 50 ml/h (same as for professional use)
- Inhalation exposure: 0.02 ml/h (same as for professional use)
- Work rate: 0.01 ha/day
- Duration of spraying: 0.5 h

German Model (Home and allotment garden area)

The basis of this model are raw data from studies generated by industry. Analysis of the exposure data revealed logarithmic-normal distributions of exposure; thus, the geometric mean is used to calculate the means of specific exposures. Exposures, D(ermal) and I(nhalation), are expressed as mg/kg of active substance.

Depending on the type of formulation, the following surrogate values have been set for the mixing/loading phase:

- Liquid
  - Dermal hand: 205 mg/kg as
  - Inhalation m/l: 0.05 mg/kg as
- Water soluble of dispersible granules (WG)
  - Dermal hand: 21 mg/kg as
  - Inhalation m/l: 0.02 mg/kg as
- Wettable powder (WP)
  - Dermal hand: 50 mg/kg as
  - Inhalation m/l: 0.8 mg/kg as

In all three cases and regarding the application phase, the following are considered:

- Dermal hand: 10.6 mg/kg as
- Dermal body: 25 mg/kg as
- Dermal head: 4.8 mg/kg as
- Inhalation appl.: 0.3 mg/kg as
- Treated area per day: 0.05 ha/day

Garden exposure model (UPJ model)

The Union des Entreprises pour la Protection des Jardins et des Espaces Publics (UPJ) has developed the "Garden exposure model" for assessing exposure of a non-professional user. The model consists of an excel spreadsheet containing the exposure equations and the raw data, along with some documentation. The model is not freely available but can be requested from UJP.

The model follows the same approach as an operator exposure model but focuses on non-professional use of plant protection products. This empirical model is based on a study in which operator exposure when using non-professional garden application equipment was measured. This study was conducted according to the Good Laboratory Practices in the

South-east of France during autumn 2003 in order to measure the dermal and inhalation exposure of non-professional gardeners during various mixing/loading and application tasks known as being representative of treatment activities in gardens. The following tasks were measured:

Mixing/loading from a:

- Liquid formulation (EW);
- Powder formulation (WP);

Application of:

- A ready-to-use liquid (AL) using a manual trigger sprayer (750 ml);
- A spray using a pre-pressure manual sprayer (5 L) on:
  - Groups of low plants and vegetable garden (downward application, below 60 cm)
  - Non cultivated permeable area (downward application, below 60 cm)
  - Hedges or free shaped trees (upward application, higher than 60 cm);
- Granules on lawn (hand application).

Four types of formulations were used:

- ✓ A ready-to-use liquid (AL)
- ✓ An emulsion, oil in water (EW)
- ✓ A wettable powder (WP)
- ✓ A granule (GR).

The exposure values were normalised as µL of formulation (or spray) per task in the case of liquids. For solids (wettable powder or granules), the values were normalised as mg formulation/task. The model can be used to evaluate the following formulation types: WP, SP, WG, SG, WSB (water soluble bag), liquid (including AL) and GR.

Three exposure scenarios are considered (with or without gloves) to determine the operator exposure and risk: (1) No gloves during mixing/loading and application; (2) Gloves during mixing/loading 2; (3) Gloves during mixing/loading and application.

3.3.2 Models to assess BYSTANDER/RESIDENT exposure

German Guidance - Martin et al., (2008) – Home and allotment garden area (HG)

A guidance for calculating exposure of bystanders and residents, has been published by Martin *et al*. (2008). The output of this guidance is a generic model algorithm in the form of an excel calculator, in which a scenario, assessing bystanders' and residents' exposure

after pesticide application in the non-professional home and allotment garden area, has been included.

The excel file is publicly available and can be downloaded *via* the following link: https://www.bfr.bund.de/cm/343/schutz_von_nebenstehenden_und_anwohnern_v1.xls

In case of **bystanders** the following equations have been considered for calculating exposure:

Dermal Exposure Model (Spray Drift)

$SDE_B = (AR \times D \times BSA \times DA) / BW$

Where:

SDE_B= Systemic Exposure of Bystanders via the Dermal Route (mg/kg bw/day)
AR = Application Rate (mg/m^2)
D = Drift (%)
BSA = Exposed Body Surface Area (m^2)
DA = Dermal Absorption (%)
BW = Body Weight (kg/person)

Inhalation Exposure Model (Spray Drift)

$SIE_B = (I_A^* \times AR \times A \times T \times IA) / BW$

Where:

SIE_B = Systemic Exposure of Bystanders via the Inhalation Route (mg/kg bw/day)
I_A = Specific Inhalation Exposure (mg/kg a.s. handled per day)*
AR = Application Rate (kg a.s./ha)
A = Area Treated (ha/day)
T = Time [Duration] (min)
IA = Inhalation Absorption (%)
BW = Body Weight (kg/person)

Total Systemic Exposure of Bystanders

Adults and Children: $SE_B = SDE_B + SIE_B$ (mg/kg bw/day)

In case of **residents** the following equations have been considered for calculating exposure:

Dermal Exposure Model (via deposits caused by spray drift, based on PSD, 2008)

$SDE_R = (AR \times D \times TTR \times TC \times H \times DA) / BW$

Where:

SDE_R = Systemic Exposure of Residents via the Dermal Route (mg/kg bw/day)
AR = Application Rate (mg/cm^2)

D = Drift (%) [1]
TTR = Turf Transferable Residues (%) [2]
TC = Transfer Coefficient (cm^2/hour) [3]
H = Exposure Duration (hours) [4]
DA = Dermal Absorption (%)
BW = Body Weight (kg/person)

Inhalation Exposure Model (Vapour Drift)

$SIE_R = (AC_V \times IR \times IA) / BW$

Where:

SIE_R = Systemic Exposure of Residents via the Inhalation Route (mg/kg bw/day)
AC_V = Airborne Concentration of Vapour (mg/m^3)
IR = Inhalation Rate (m^3/day)
IA = Inhalation Absorption (%)
BW = Body Weight (kg/person)

Child Oral Exposure

Children's Hand to Mouth Transfer Exposure Model (based on PSD, 2008)

$SOE_H = (AR \times D \times TTR \times SE \times SA \times Freq \times H \times OA) / BW$

Where:

SOE_H = Systemic Oral Exposure via the Hand to Mouth Route (mg/kg bw/day)
AR = Application Rate (mg/cm^2)
D = Drift (%) [5]
TTR = Turf Transferable Residues (%) [6]
SE = Saliva Extraction Factor (%) [7]
SA = Surface Area of Hands (cm^2)[8]
Freq = Frequency of Hand to Mouth (events/hour)[9]
H = Exposure Duration (hours) [10]
OA = Oral Absorption (%)

[1] If multiple applications have to be taken into account, e.g. the 82nd percentile needs to be considered for twice the application rate.
[2] A default value of 5 % derived from transferability studies with wet hands is recommended (US EPA, 2001).
[3] Default values of 7300 cm^2/hour for adults and 2600 cm^2/hour for children are recommended (values for 2 hours of exposure, US EPA, 2001).
[4] A default value of 2 hours is recommended (US EPA, 2001).
[5] If multiple applications have to be taken into account, e.g. the 82nd percentile needs to be considered for twice the application rate.
[6] A default value of 5 % derived from transferability studies with wet hands is recommended (US EPA, 2001).
[7] A default value of 50 % is recommended (US EPA, 2001).
[8] The assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (US EPA, 2001).
[9] For short term exposures the value of 20 events/hour is recommended, this is the 90th percentile of observations ranging from 0 to 70 events/hour (US EPA, 2001).
[10] A default value of 2 hours is recommended (US EPA, 2001).

BW = Body Weight (kg/person)

Children's Object to Mouth Transfer Exposure Model (based on PSD, 2008)

SOE_O = (AR x D x DFR x IgR x OA) / BW

Where:

SOE_O = Systemic Oral Exposure via the Object to Mouth Route (mg/kg bw/day)
AR = Application Rate (mg/cm^2)
D = Drift (%)
DFR = Dislodgeable Foliar Residues (%) [11]
IgR = Ingestion Rate for Mouthing of Grass/Day (cm^2) [12]
OA = Oral Absorption (%)
BW = Body Weight (kg/person)

Total Systemic Exposure of Residents

Adults: $SE_R = SDE_R + SIE_R$ (mg/kg bw/day)

Children: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$ (mg/kg bw/day)

For the non-professional applications in the home and allotment garden area, the drift values published in the Federal Gazette (2003) (cf. Rautmann *et al*., 2001, current version 27.03.2006) have been used Table 1: Percent Drift Values for Non-Professional Use in the Home and Allotment Garden Area(Table 1). The recommended distances are 1 m for low crops and 3 m for high crops:

Table 1: Percent Drift Values for Non-Professional Use in the Home and Allotment Garden Area

Crop, Distance	**Percent Drift (1 application) (90th percentile values)**	**Percent Drift (2 applications) (82nd percentile values)**
Low crops, e.g. bed (< 50 cm), 1 m	0.42	0.19
High crops, e.g. trees, late, 3 m	3.53	2.12
High crops, e.g. trees, early (≤ 2 m), 3 m	13.52	9.11
High crops, e.g. trees, early (> 2 m), 3 m	38.09	27.75
High crops, e.g. vegetables, berry fruits, ornamentals (> 50 cm), 3 m	0.72	0.52

The area treated is considered to be 0.05 ha.

[11] A default value of 20 % transferability for object to mouth assessments is recommended (US EPA, 2001).
[12] A default value of 25 cm^2 of grass/day is recommended (US EPA, 2001).

US EPA Standard Operating Procedures

In addition to the exposure scenarios in outdoor location in residential setting outlined above other exposure scenarios relevant for residents (child) were found to be available in the US EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment. These include the incidental soil ingestion containing pesticide residues and post application incidental ingestion of pesticide pellets and granules that have been applied to lawns and gardens when adequate site-or chemical-specific field data are unavailable. For both these scenarios approaches and methodologies are available to estimate the exposure (US EPA SOP 2012).

It is pointed out that for the weed wiping application no exposure data were retrieved.

Additional exposure determinants, specific for residential settings, to assess residents' post application exposure through dermal contact with different type of treated crops and during different tasks (turf, gardens, trees, retail plants and grass mowing) were retrieved from the US EPA standard operating procedure (SOP) for residential pesticide exposure assessment (Table 2).

Table 2: Outdoor exposure determinants to assess post application dermal exposure of residents

Turf	TC[1]	L/WP/WDG	Adults	180.000
			Children 1 < 2 years old[a]	49.000
		Granules	Adults	200.000
			Children 1 < 2 years old[a]	54.000
	T	Adults		1.5
		Children 1 < 2 years old[a]		1.5
	TTR	L/WP/WDG		0.01
		Granules		0.002
Garden	TC[2]	Adults		8400
		Children 6 < 11 years old		4600
	T	Adults		2.2
		Children 6 < 11 years old		1.1
	DFR			0.25
Trees and retail plants	TC[3]	Adults		1700
		Children 6 < 11 years old		930
	T	Adults		1.0
		Children 6 < 11 years old		0.5
	DFR			0.25
Grass/turf mowing	TC[4]	Adults		5500
		Children 11 < 16 years old		4500
	T	Adults		1
		Children 11 < 16 years old		
	TTR	L/WP/WDG		0.01
		Granules		0.002

TC: transfer coefficient (cm^2 per hour); T: exposure time (hours per day); TTR: turf transferable residue (fraction) assuming no residue degradation over time; DFR: dislodgeable foliar residue (fraction) assuming no residue degradation over time; L/WP/WDG: liquids/wettable powders/water-dispersible granules

1: data were generated in a study which enrolled 40 participants that were monitored in two type of physical activities; one consisting of several children's activities (1 to 12 years) and the second one of choreographed routine of exercises performed with music. a: 73% reduction in the adult transfer coefficient is recommended because of the differences of body surface areas between adults and children 1 < 2 years old.
2: Transfer coefficient derived from four separate studies representing residential gardening activities (weeding and picking flowers, fruits, or vegetables). These TCs are also applicable for activities in "pick-your-own" farms growing field grown crops (e.g., pumpkins, strawberries, etc.).
3: Transfer coefficient derived from four separate studies representative for activities on threes (picking roses or apples or thinning shrubs and bushes) and retail plants previously treated with pesticides at commercial locations. These TCs are also applicable for activities in "pick-your-own" farms growing tree crops (e.g., apples, some flowers, etc.).
4: Transfer coefficient derived from human volunteers (i) mowed greens with a walk-behind mower and (ii) mowed fairways with a riding mower on a golf course. Activities with both walk-behind and riding mowers included emptying the grass catcher and hosing off the mower with water at the conclusion of mowing.

3.3.3 Models to assess USER re-entry exposure

Currently, no specific model or harmonized approach is available for the assessment of the worker exposure related to non-professional use of pesticides. Thus, different approaches are followed by MSs.

One of the approaches considered more recently and applied also within the EFSA peer review, is the use of the generic formula used for worker exposure assessment in case of professional use of PPS, according to the EFSA Guidance (2014), but taking into account a lower work rate, i.e.:

$$\text{Total systemic exposure} = (DFR * TC * WR * AR * MAF * DA) / BW * 1000$$

Where:

- DFR = Dislodgeable foliar residue (μg/cm^2 per kg a.s./ha)
- TC = Transfer coefficient according to the relevant task (cm^2/h)
- WR = Working rate (For non-professional use on home and allotment garden area a working rate of 2 hours/day is assumed)
- AR = Application Rate (kg a.s./ha)
- MAF= Multiple application factor
- DA = Dermal absorption (%)
- BW = Body weight (60 kg)

3.3.4 Guidance for non-dietary exposure assessment

German guidance proposal for Central Zone: Amateur/non-professional use in home gardens – exposure assessment

Currently, an EU harmonized guidance for the assessment of exposure related to non-professional use of pesticides is not available. However, an initiative has been undertaken within the Central Zone Steering Committee by developing a document, where all the available data and models are compiled, and guidance is provided on the most relevant

calculation tool depending on the examined exposure scenario. This document has been further discussed at interzonal level and an agreement is expected to be reached in the near future (Note: to be amended when finalizing the document if there is any development at the level of interzonal Steering Committee)

For non-professional use of PPPs, the values for inhalation rates, bodyweights and body surface areas proposed in the EFSA Guidance (2014) may be applied. An average area of 0.05 ha is proposed, based on a survey amongst garden owners in Germany between 2015 and 2016

(https://service.ble.de/ptdb/index2.php?detail_id=49093&site_key=141&stichw=14SE002&zeilenzahl_zaehler=1#newContent). The work duration is assumed to be 30 min.

For the non-professional operator, the following scenarios in relation to the type of application, are considered: granule spreading, ready-to-use (RTU) products for spray application, compression or pump sprayers (5-20 L), watering, weed wiping, brush painting, sticks, and greenhouse spraying. The models to assess the exposure proposed for each of the above scenarios are presented in the following table (Table 3):

Table 3: Models for assessing the exposure of non-professional user of PPPs

Application techniques	Application equipment or product formulation	Task	Model
Granule spreading	Shaker pack	Mixing/Loading & Application	UK Puffer pack model
	Push along spreader	Mixing/Loading & Application	Pesticide Handlers Exposure Database (PHED) data from EFSA GD (2014) push along and handheld spreading combined
	Hand operated spreading	Mixing/Loading & Application	
	Hand spreading	Mixing/Loading & Application	UPJ model
			US EPA Residential SOPs
Spray application of Ready-to-use (RTU) products	Trigger sprayer	Application	Consumer product spraying and dusting model 2 (surface)
		Application	Consumer product spraying and dusting model 1 (space)
		Application	UPJ model
	Pre-pressurised aerosol can	Application	Consumer product spraying and dusting model 2 (surface)
		Application	Consumer product spraying and dusting model 1 (space)
Compression or pump sprayers (5-20 L)	Liquids	Mixing/Loading	UK data
			UPJ model
			AOEM LCHH (knapsack)

		Application downwards	UPJ model
		Application upwards	AOEM HCHH (knapsack)
			UPJ model
	Granules	Mixing/Loading	AOEM knapsack
		Application downwards	AOEM LCHH (knapsack)
			UPJ model
		Application upwards	AOEM HCHH (knapsack)
			UPJ model
	Powders	Mixing/Loading	AOEM knapsack
			UPJ model
		Application downwards	AOEM LCHH (knapsack)
			UPJ model
		Application upwards	AOEM HCHH (knapsack)
			UPJ model
Watering	-	-	Sub-soil treatment model 2
Weed wiping	Hand-held rope-wick applicator	-	No exposure data available; exposure applications covered by corresponding spray applications with same or higher application rate
	Push along weed wiper	-	
Brush painting	RTU products, Concentrated products	Mixing/Loading	Hand exposure → UK data; Inhalation and dermal exposure → AOEM (knapsack)
		Application	Painting model 3. ACP - SC 11000 - consumer exposure to non-agricultural pesticide products
		Cleaning	HEEG opinion 11 on exposure model (2010)
Sticks	-	-	Considering 4 cm^2 of the hands exposed and 20% transfer from surface
Greenhouse spraying	-	-	Professional models adjusted for smaller areas, *i.e.* 35 m^2

In case a refinement of the operator exposure is necessary, a reduction of the potential dermal exposure by a factor of 0.5 for gloves and 0.5 for clothing covering legs and arms is proposed. It is noted though, that the use of gloves or clothing is not acceptable by all MS.

For non-professional workers, an assessment of the exposure is proposed to be carried out with the EFSA model (2015), considering a working time of 2 hours for all re-entry activities and the respective transfer coefficients (TC) for potential exposure. The use of

long trousers, long sleeved shirt and gloves, as well as the setting of a re-entry period are not considered realistic for re-entry of non-professional workers in the garden. In case of granule applications, the exposure from contact with the residues of the treated soil can be estimated, according to the EFSA GD (2014).

For bystanders and residents, the exposure durations are the same as the ones proposed in the EFSA GD (2014). In addition, entry into treated crops is also assumed to be the same for professional and non-professional use. Data for surface deposits in home gardens and allotment gardens are available in DE (https://www.julius-kuehn.de/at/ab/abdrift-und-risikominderung/abdrifteckwerte/) and can be used instead of the data provided in the EFSA GD (2014). However, the drift is lower and the default vapour concentrations described in the EFSA GD (2012) have been obtained for large treated fields. In case of lawn, the recreational exposure should also be assessed. Finally, a refinement of the bystander/resident exposure is not possible considering drift reduction measures and safety distances.

Guidance in non-EU MSs

Regarding the available guidance in non-EU countries, reference should be made also to the UK (HSE) guidance documents for amateur operator exposure, i.e. the Operator exposure guidance for amateur (home garden) pesticides (https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/amateur-use-guidance.doc) and the document providing information on operator exposure considerations for pesticide containers [*Pesticide containers: guidance on operator exposure considerations*; https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/packaging-guidance.doc].

3.3.5 Results of open literature search

Detailed results of the open literature for available exposure data/methodologies relevant to non-professional use of pesticides search are shown in Table 4:

Table 4: Open Literature search for exposure data/methodologies relevant to non-professional use of PPPs

Search string	**SCOPUS** document results	**Included/Not considered**
TITLE-ABS-KEY(amateur OR non-professional) AND ("plant protection product" OR pesticide) AND exposure	14	Included
TITLE-ABS-KEY(residential AND ("plant protection product" OR pesticide) AND exposure)	718	Not considered; When screening the search results, it was observed that the reference to residential exposure was related mostly to exposure of residents in agricultural areas and not due to use of PPPs by non-professionals.
TITLE-ABS-KEY("residential exposure" AND ("plant protection product" OR pesticide) AND exposure)	133	
TITLE-ABS-KEY(amateur OR operator) AND exposure AND pesticide)	328	Not considered;

TITLE-ABS-KEY((operator OR worker OR farmer) AND amateur AND exposure AND pesticide)	2	When screening the search results, it was observed that these were mainly related to professional use of PPPs.
TITLE-ABS-KEY((operator OR worker OR farmer) AND amateur AND exposure AND ("plant protection product" OR pesticide))	2	
TITLE-ABS-KEY((operator OR worker OR farmer) AND exposure AND ("plant protection product" OR pesticide))	5221	
TITLE-ABS-KEY(operator OR worker OR farmer) AND exposure AND ("plant protection product" OR pesticide) AND (amateur OR 'non-professional'))	8	
ALL (amateur OR 'non-professional') AND **TITLE-ABS-KEY** ((operator OR worker OR farmer) AND exposure AND ("plant protection product" OR pesticide))	23	Included
ALL (amateur OR 'non-professional') AND **TITLE-ABS-KEY** (exposure AND ("plant protection product" OR pesticide))	56	Included
TOTAL (before relevance check)	93	Before duplicate check
	56	After excluding duplicates
TOTAL (after relevance check)	**13**	Excluding those not relevant to non-dietary exposure even from the title & abstract screening.

Overall, 56 references have been identified as potentially relevant to non-professional use of pesticides and exposure data/methodologies. Following a relevance check *via* screening the title – abstract, only thirteen (13) references have been considered as relevant to the specific search objective. For the relevance check an EndNote library has been used.

The thirteen (13) references have been reviewed in detail. It is noted that one of the relevant documents identified by the SCOPUS literature search was the OPEX EFSA Guidance (2014); this has not been presented since it has been considered that this is out of the scope of this review. It is acknowledged, however, that the EFSA Guidance on the non-dietary exposure assessment to pesticides, the one currently in use as well as the updated one that is to be published soon, include elements that can also be considered for the assessment of residential exposure to pesticides.

The UK Health and Safety Executive (HSE) perspective[3] on assessing the dermal exposure to pesticides from non-agricultural uses has also been identified by the search conducted. Since the UK approach for the assessment of exposure to PPPs has been already presented in the previous section, this has not been further considered.

Although limited exposure data related to non-professional use of PPPs have been identified, there is contextual information that can be further considered for the exposure pathways and determinants to be taken into account when developing the specific exposure scenarios. Part of the retrieved publications is relevant to residential use of biocides and not PPPs.

In one of the publications retrieved (Beránková, *et al.*, 2017a) the term "*Estimated Gardener Exposure Level*" (EGEL) was introduced, which was used for the estimation of the systemic exposure following dermal exposure mainly based on the dermal absorption. The worst-case scenario of potential systemic exposure of a gardener that would occur through the skin when applying the PPPs without using any personal protective equipment. Beránková *et al*. (2017a) have considered the concept of Systemic Exposure Dose used in the safety assessment of cosmetic ingredients (SCCS, 2016) as a basis for the determination of the EGEL value. The approach was adopted in order to be used for pesticides and the following equation was used for the calculation of exposure:

$$EGEL = \frac{DA(\mu g/cm^2) \times 10^{-3}(mg/\mu g) \times C \times SSA(cm^2)}{70(kg)}$$

where:

EGEL is the Estimated Gardener Exposure Level (mg/kg bw/day) for 1 h or 24 h after the exposure of unprotected body's skin;

DA is the dermal absorbed dose of the test substance (µg/cm^2) as measured *in vitro*, *i.e.* the amount in the receptor fluid and in the skin;

C is the coefficient permeability through fresh/frozen-stored full-thickness skin for the test substance;

SSA is the skin surface area of the body part expected to be exposed (cm^2); 1070 cm^2 for both hands and 1480 cm^2 for both forearms (Paustenbach and Madl, 2014), as representative mean surface areas of body portions for 21 year old adult male and older (total body area of 20,600 cm^2);

70 kg is the default body weight for an adult (above 18 years old).

The above presented estimation, although is based on principles that seem similar to other deterministic approaches followed for the calculation of the non-dietary exposure *via* the dermal route, differs significantly since it takes into account not the potential dermal exposure but the amount of substance that is absorbed per surface area. This approach might be relevant for cosmetics which applied on the skin and there is a recommended dose of application, however, the relevance to pesticides is questioned. Overall, based on the retrieved open literature, it was concluded that there is only limited data available related to non-dietary exposure to pesticides used by non-professional users.

3.4 Existing data and exposure methodologies for BPs exposure assessment in residential settings.

Ad hoc Working Group on Human Exposure (HEAdhoc)

The HEAdhoc prepares recommendations on issues concerning human exposure related issues for which a harmonised approach across the EU is desirable. Table 5 shows recommendations which are relevant to estimate the consumer exposure under certain conditions and which are considered useful in exposure assessment of PPPs. Note that the HEAdhoc recommendations are an integral part of the Biocides methodology.

Table 5: HEAdhoc recommendations relevant for exposure assessment of PPPs in residential settings

Document	Description	Models	Relevance to PPP scenario
Recommendation 3 - Spraying models for assessing exposure to insecticides for low pressure downward uses.	The question as to whether it is possible to refine the spraying model 1 of the TNsG 2002 with BEAT spraying models in the context of professional exposure to insecticides was put forward to the former HEEG (Human Exposure Expert Group). Based on the work started by HEEG, the present recommendation was prepared by the Ad hoc Working Group on Human Exposure.	Mixing and loading liquids and powders in compression sprayers or dusting applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards. Scenario: low pressure insecticide application	Low pressure downwards spraying in gardens and greenhouse
Annex to recommendation 3 - Studies with spraying applications PT18 (Insecticides, acaricides and products to control other invertebrates)	The studies with spraying applications for insecticide applications or close to insecticide applications from BEAT, RISKOFDERM and ART	BEAT, RISKOFDERM and ART	Low pressure downwards spraying in gardens and greenhouse
Recommendation 5 - Non-professional use of antifouling paints: exposure assessment for a toddler	The aim of this recommendation is to assess the systemic exposure of a toddler touching antifouling paints on a treated surface in the following situations: • Dermal exposure to wet paint • Oral exposure to wet paint through hand-to-mouth transfer • Dermal exposure to dried paint • Oral exposure to dried paint through hand-to-mouth transfer The scenarios considered in this document refer to antifouling containing paints, but may also be relevant for uses of other types of paint. For antifouling paints, all of the four exposure scenarios	• Dermal exposure to wet paint • Oral exposure to wet paint through hand-to-mouth transfer • Dermal exposure	Application by brush Secondary exposure via hand contact of wet and dry surfaces Secondary exposure via hand to mouth behavior

Document	Description	Models	Relevance to PPP scenario
	(dermal and oral) for wet and dried paint apply. A tiered approach is presented.	to dried paint • Oral exposure to dried paint through hand-to-mouth transfer	
Recommendation 6 - Methods and models to assess exposure to biocidal products in different product types	This recommendation, based on a concept paper prepared by the Netherlands, aims at proposing methods and models for a harmonised exposure assessment to biocides in different product types.	Summary of models	Covers basically all types of applications that are relevant for PPP exposure. Recommendation 6 provides the preferred models in case multiple options exist.
Annex - PT18 (Insecticides, acaricides and products to control other invertebrates) professional exposure		Spraying models professionals as proxy for non-professional	Spraying applications
Recommendation 8 - Consumers protection factor from clothing	The aim of this recommendation is to address the following three main questions: 2.1 What is typical clothing in the frame of a reasonable worst-case scenario? 2.2 How to assess the protection factor provided by clothing? 2.3 How to integrate the protection factor in the models from the TNsGs? Please note that this recommendation concerns only protection from typical clothing and does not cover the use of gloves.	Addresses use of cloth protection for non-professionals	Relevant for all scenarios. It concerns typical clothing and how normal clothing provides protection against exposure. Not only uncovered skin is exposed.
Recommendation 10 – The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling	The aim of this recommendation is to suggest the most appropriate model for assessing non-professional painting by brush or roller when using PT7 or PT8 products. The mixing and loading and cleaning of the brush are not discussed in this recommendation. Applicable models concerning exposure assessment of mixing and loading are given in Biocides Human Health Exposure Methodology document (2015). Exposure model for cleaning a brush is given in the HEEG opinion 11 'Exposure model - washing out of a brush'. This recommendation does not apply to brush/roller application of antifouling paints by the non-professionals. For this scenario a specific model is given in the Biocides Human Health Exposure Methodology document (Non-professionals brushing and roller painting antifouling paint on underside of small boats, outdoor).	Models brushing and rolling	Brushing applications like tree bark treatment.
Recommendation 12 - Default	This recommendation describes the way US EPA, in 2012, derived the new default transfer coefficient	Models for transfer of	Secondary exposure

Document	Description	Models	Relevance to PPP scenario
values for indoor Transfer Coefficient	value, describes underlying data, highlights some points for consideration, and finally provides a recommendation for a transfer coefficient value default to be used in exposure assessments under the Biocides framework	pesticides from treated surfaces	through hand contact and subsequently hand to mouth behaviour
Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products	This recommendation is to promote a harmonised approach to biocide exposure assessment across Member States. Appendix A gives the agreed list of default human factors for the 'infant', 'toddler', 'child' and 'adult' (irrespective of gender) to be used in exposure/risk assessments for biocidal products.	harmonisation Biocides, pesticides and reach	Anthropometric data. Useful to achieve harmonisation.
Recommendation 15 - Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer.	This document focuses on the exposure assessment for rapid in-between disinfection of small surfaces only (e.g. work bench) using volatile active substances and application patterns with trigger sprayer and RTU wipes. In addition, the assessments presented in this document concentrate mainly on inhalation exposure.	models for trigger sprays	Trigger sprays and RTU wipe products.

Biocides Human Health Exposure Methodology

In the Biocides Human Health Exposure Methodology (2015) the following list of exposure scenarios are suitable for specific product types and might be relevant to assess non-professional exposure to PPPs. The details of the scenario and the recommended methods/models for non-professional users are provided in Appendix A for the following product types and exposure scenario:

- Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals.
  - Non-Professional pond treatment
- Product type 3 - Veterinary hygiene
  - Non-professional animal house disinfection by spraying.
- Product type 6 - Preservatives for products during storage
  - Non-professional manual paint spraying (paints, inks, polymer emulsions)
  - Non-professional indoor wall plastering
- Product type 18 - Insecticides, acaricides and products to control other arthropods.
  - Non-professional scattering powder against ants from a flexible duster/hand-held canister by consumers.
  - Non-professional use of insecticide cassettes.

Pest Control products and Disinfectants products Fact sheets

The following Table 6 information was distilled from the Pest Control products and Disinfectants products Fact sheets from RIVM.

Table 6: Models to describe the mixing and loading, the exposure during and after spray application

Situation		Spray type	Route of exposure		
			Inhalation	Dermal	Oral
Mixing and loading	Dilution of liquid Dissolving a powder/granules		Evaporation	Instant application Constant rate	
During application	Targeted spot Crack and crevice General surface Air space Pouring and brushing Dusting powder / granules Baits? Disinfectants of private swimming pools	Spray can/trigger spray Spray can/trigger spray Spray can/trigger spray Spray can Spray- instant release	Spray Spray Spray Spray Evaporation Spray Constant rate	Constant rate Constant rate Constant rate Constant rate Constant rate Instant or constant Instant	Spray Spray Spray Spray
After application (post-application exposure of children)	Targeted spot Crack and crevice General surface Air space			Rubbing off Rubbing off Rubbing off Rubbing off	Hand-mouth Hand-mouth Hand-mouth Hand-mouth

The models that describe the spray applications are the same for the four different methods of spraying (targeted spot, crack and crevice, general surface and air space). The spray model is developed on the basis of the results of experimental work and describes the indoor inhalation exposure to slightly evaporating or non-volatile compounds in droplets that are released from a spray can or trigger spray. For volatile substances, the evaporation model is more appropriate. If the spray model is used for volatile substances the inhalation exposure will be underestimated, because exposure to vapour is not considered in the spray model. Volatile is defined as compounds with vapour pressure > 0.1 Pa, non-volatile < 0.01 Pa and slightly volatile between 0.01 and 0.1 Pa).

3.5 Assessment of results and data-gap identification

The exercise of retrieving the available data and methodologies to assess non-dietary exposure in residential setting considered the outdoor, greenhouse and indoor locations, and the user, "user re-entry", resident and the bystander as individuals that are directly or indirectly exposed to PPPs.

3.5.1 Outdoor

For the outdoor location a reasonable number of exposure models and approaches to assess the exposure of the user were identified. Overall, based on products for non-professional use authorized in Italy, Greece and the Netherlands, the models cover an adequate range of products of non-professional settings, such as ready to use products, concentrate formulations of solids and liquids, and applications to low- or high-level targets. The retrieved models allow as well the exposure assessment for the different tasks in which PPPs are handled during their preparation and application; also taking into consideration specific non-professional exposure determinants for decanting of concentrates (e.g: in cup measure, separate measure), volumes of sprayed formulations (knapsack and trigger sprayers), default values for treated areas and duration of spraying.

Additionally, exposure scenarios of the user for other application types were identified, such as watering, weed wiping, paint brushing and sticks insertion. For weed wiping products no exposure data is available. A schematic outline of the models retrieved is presented in Table 7.

Table 7: Available models to assess user exposure in outdoor locations

Outdoor [a]				
USER				
Formulation	**Application techniques or product formulation**	**Application equipment**	**Task**	**Model(s)**
Solid	Granule spreading	Shaker pack	Mixing&Loading/Application	UK puffer pack
		Push along	Mixing&Loading/Application	Pesticide Handlers Exposure Database (PHED) data from EFSA GD (2014) push along and handheld spreading combined
		Hand operated spreading	Mixing&Loading/Application	
		Hand spreading	Mixing&Loading/Application	UPJ French model US EPA Residential SOPs
	Granules	Compression or pump sprayers (5-20L)	Mixing&Loading	AOEM knapsack
				UK POEM "home garden"[b]
			Application downward	AOEM LCHH (knapsack)
				UPJ French model
				UK POEM "home garden"
			Application upward	AOEM HCHH (knapsack)
				UPJ French model
				German model
	Powders		Mixing&Loading	AOEM knapsack
				UPJ French model
				German model[d]
				UK POEM "home garden"[e]
			Application downward	AOEM LCHH (knapsack)
				UPJ French model
				UK POEM "home garden"
			Application upward	AOEM HCHH (knapsack)
				UPJ French model
				German model
	Ready to Use (RTU) dustable powder		Application	Puffer pack model
Liquids	Spraying	Compression or pump	Mixing&Loading	UK POEM "home garden"[c]
				UPJ French model
				AOEM model

Outdoor [a]				
USER				
Formulation	**Application techniques or product formulation**	**Application equipment**	**Task**	**Model(s)**
		sprayers (5-20L)		German model
			Application downward	UK POEM "home garden"
				UPJ French model
				AOEM LCHH (knapsack)
			Application upward	German model
				AOEM HCHH (knapsack)
				UPJ French model
	Ready to Use (RTU)	Trigger spray	Application	UK model. Consumer product spraying and dusting model 2 (surface)
			Application	UK model. Consumer product spraying and dusting model 1 (space)
			Application	UPJ French model
		Pre-pressurized aerosol can	Application	UK model. Consumer product spraying and dusting model 2 (surface)
			Application	UK model. Consumer product spraying and dusting model 1 (space)
Additional application types				
Watering		-	-	Sub-soil treatment model 2
Weed wiping		Hand-held rope-wick applicator	-	No data
		Push along weed wiper	-	
Brush painting (RTU & concentrate)			Mixing&Loading	Hand exposure → UK data Inhalation and dermal exposure → AOEM (knapsack)
			Application	Painting model 3. ACP - SC 11000 - consumer exposure to non-agricultural pesticide products
			Cleaning	HEEG opinion 11 on exposure model (2010)
	Sticks	-	-	Considering 4 cm^2 of the hands exposed and 20% transfer from surface

HCHH: high crop hand held; LCHH: low crop hand held
[a]: Garden, vegetable garden, Cereals/olive/grapes (as representative of different typologies of crops farmed on wider surfaces) and lawns;
[b]: exposure values for water dispersible granules (WG), water soluble granules (SG);
[c]: exposure values for (i) in-cap measure (ii) separate measure (iii) squeeze to fill measuring chamber;
[d]: exposure values not based on data;
[e]: exposure values extrapolated from WG.

To assess post application exposure of the resident and bystander, the guideline and methodology published by Martin *et al.* 2008 has been identified. Although this model has been used for several years in the past as a reference model to assess exposure of residents and bystanders in the context of professional use of PPPs, it includes exposure determinants (drift values) generated for non-professional use of PPPs in home and

allotment garden area. It is noted that updated transfer coefficients (TC) for post application dermal exposure of adult and child were available, accounting for typical certain residential activities differentiated for lawns and garden (Table 2). The transferable residue from plants/crops other than turf to assess child oral exposure resulting from accidental mouthing of contaminated hands is lacking.

The model identified to assess post application exposure resulting from user re-entering activities into treated crops/plants is the one typically used to assess this exposure scenario in case of professional use of PPPs according to the EFSA guidance (2014), with the assumption of a reduced work rate (2 hours) for non-professionals.

The model to assess the exposure resulting from accidental (bystander and resident) re-entry into treated crop/plans is the same used for the user re-entry activities using however, TCs from professional inspection and a reduced exposure time. In this context more specific TC to residential settings were scouted (Table 2).

3.5.2 Greenhouse

The exposure assessment for the greenhouse scenario can be performed using professional models assuming reduced surfaces (*i.e.* 35 m^2). For this scenario the exposure is estimated for the user during mixing & loading (if needed), the application and re-entry activities. Bystanders are unlikely to be present during application, and residents (adult and child) exposure should be considered as for the indoor scenario accounting however probably only for the entry into treated crops.

3.5.3 Indoor

For indoor location, a reasonable number of exposure models and approaches to assess the exposure of the user were identified. Overall, based on products for non-professional use authorised in Italy, Greece and the Netherlands, the models cover an adequate range of products of non-professional settings, such as ready-to-use products and concentrate formulations of solids and liquids. The retrieved models allow the exposure assessment as well for the different tasks in which PPPs are handled during their preparation and application. Additionally, models to assess the exposure of the user for other application types were identified, such as paint brushing, sticks insertion, dipping of plant portions/cuttings. Overall, no substantial data gaps were identified to assess the exposure of the user in indoor settings. A schematic outline of the models retrieved is presented in Table 8.

Table 8: Available models to assess user exposure in the indoor scenario

Application techniques	Application equipment or product formulation	Task	Model
Soil insertion (sticks)	dry solid plant rodlet (RTU)	Manual insertion	Only Dermal exposure ConsExpo Web: dermal exposure – instant contact
Granules spreading	Hand spreading (RTU)	Application	PHED (Pesticide Handler Exposure Database) Scenario 17 "Granular bait dispersed by hand" TNsG 2007 Hand-held flexible duster
			AOEM manual application of granules outdoor ConsExpo Web: spray exposure – instant release
Spray application of Ready-to-use (RTU) products	Trigger sprayer	Application	Trigger spray surface treatment model ConsExpo Pest control targeted spot: trigger spray: spray model Dermal model: constant rate HEAdhoc recommendation 15
	Pre-pressurized aerosol can	Application	Consumer product spraying and dusting model 2 (surface) ConsExpo Pest control targeted spot: spray can: spray model Dermal model: constant rate
Dipping	powder	Manually dipping	Data for hand contamination during M/L from UK-poem home garden scenario ConsExpo Web Pest Control product, mixing and loading powders
	Liquid	Manually dipping	Data for hand contamination during M/L from UK-poem home garden scenario ConsExpo web Cleaning agents fact sheet on mixing and loading of liquids.
Spraying	liquid	Mixing/Loading	UK-poem "home garden"[a]
			UPJ model
		Application	Trigger spray surface treatment model ConsExpo Pest control targeted spot: trigger spray: spray model Dermal model: constant rate HEAdhoc recommendation 15
	granules	Mixing/Loading	AOEM knapsack
			UK-poem "home garden"[b]

Application techniques	Application equipment or product formulation	Task	Model
		Application	Trigger spray surface treatment model ConsExpo Pest control targeted spot: spray can: spray model Dermal model: constant rate
	powder	Mixing/Loading	AOEM knapsack
			UK-poem "home garden"[c] ConsExpo Web Pest Control product, mixing and loading powders
		Application	Trigger spray surface treatment model ConsExpo Pest control targeted spot: trigger spray: spray model Dermal model: constant rate HEAdhoc recommendation 15
Painting/brushing	paste	Application	TNsG2007 (Consumer exposure data: brushing, Brushing and roller) ConsExpo Paint products fact sheet (also contains TNsG data). HEAdhoc recommendation 5 & 10

[a]: exposure values for (i) in-cap measure (ii) separate measure (iii) squeeze to fill measuring chamber.
[b]: exposure values for water dispersible granules (WG), water soluble granules (SG).
[c]: exposure values extrapolated from WG

Among the US EPA and EU biocides exposure assessment guidance documents several methodologies are available to assess the exposure of residents in indoor locations were retrieved. Among the different type of application scenarios reported in biocide exposure assessment guidances, "Perimeter/Spot/Bedbug (course application); Crack and Crevice" is considered the most relevant to estimate agrochemical indoor non-professional use by spray application of liquids. The exposure parameters/determinants, and the available model(s)/approaches to assess the exposure of the resident post application indirect exposure are outlined in Table 9.

Table 9: Available exposure parameters/determinants, models and approaches for resident post application indirect exposure assessment

Exposure parameters/determinants	Values	Models/Approaches	
		US EPA	EU Biocides
Dermal exposure			
Exposure time			For adults, dermal exposure of non-professional user covers the exposure resident.
Adult	• 8 hr, carpet • 2 hr, hard surface	SOP 2012	

Exposure parameters/determinants	Values	Models/Approaches	
		US EPA	EU Biocides
Child	• 4 hr, carpet • 2 hr, hard surface	SOP 2012	For child, ConsExpo – Pest control fact sheet – post-application exposure of children – dermal – rubbing off.
Transferable residue from different indoor surfaces	• 6%, carpet	SOP 2012	-
	• 8%, hard surface	SOP 2012	-
Inhalation exposure to vapour			For the child, the exposure to vapour is considered covered by the dermal exposure to surface (see above). For adult, ConsExpo web modelling: • Model – 'Exposure to Vapour' • Mode of release – 'Evaporation' • Release area – 'Increasing'. HEAdhoc recommendation 15. The choice of model depends on the volatility of the substance that one wants to assess. In case of a volatile substance the best model to be used is: ConsExpo Pest control targeted spot: trigger spray: spray model. In the case of non-volatile substances, estimating the evaporation of the substance over time may be a more realistic scenario to estimate exposure than exposure during spraying. In that case it is best to use: ConsExpo: exposure to vapour: evaporation: increasing over time.
Inhalation exposure time			
Adult	16 hr	SOP 2012	
Child	18 hr		
Inhalation volume	0.33 m^3/hr, children 1 < 2 years old 0.69 m^3/hr, adult	SOP 2012	
Default room volume	33 m^3	SOP 2012	
	Several default values of Dutch rooms	-	ConsExpo General fact sheet. Table 6
Defaults for air volume exchange	0.45/hr	SOP 2012	
	Several values of ventilation rates of homes outside the Netherlands	-	ConsExpo General fact sheet Table 11
Children hand to mouth exposure			
Saliva extraction factor (fraction)	0.48	SOP 2012	BPC Ad hoc Working Group on Human Exposure-Recommendation 5, application by brush, secondary exposure via hand-to-mouth behaviour
Fraction of hand mouthed (child)	Surface area of one hand (150 cm^2) x Fraction of hand mouthed per event. (0.13) = 20 cm^2, Children 1 < 2 years old	SOP 2012	
	Transferable fraction of paint from hand to mounth: 10% (wet paint), 50% (dried paint)	-	
	Ingestion rate: 10% from the total dermal exposure	-	ConsExpo – oral exposure – constant rate
Replenishment intervals per hour (intervals/hr)	4	SOP 2012	-
Hand-to-mouth events per hour (events/hr)	20, Children 1 < 2 years old	SOP 2012	-
Children object to mouth exposure			
Fraction of residue transferred to an object	• 0.06, carpets • 0.08, hard surfaces	SOP 2012	-

Exposure parameters/determinants	Values	Models/Approaches	
		US EPA	EU Biocides
Surface area of object mouthed (cm^2/event)	4	SOP 2012	-
Saliva extraction factor (fraction)	0.48	SOP 2012	-
Object-to-mouth events per hour (events/hour)	14, Children 1 < 2 years old	SOP 2012	-

For the bystander no guidance documents or methodologies specific for indoor locations were retrieved. Nor the US EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment or the EU exposure methodologies applied in the framework of biocides, consider the exposure assessment of individuals (adult and child) that are within or directly adjacent the location where products' application or treatment is in process.

Given the peculiarity of the use of PPPs none of the BPs exposure assessment methodologies contemplate the exposure resulting from the user re-entry activities (post application direct exposure) indoor. The methodology/formula used for worker exposure assessment in case of professional use of PPPs outdoor, according to the EFSA Guidance (2014) is considered adequate but using specific activity rate and transfer coefficient specific for indoor settings.

$$\text{Total systemic exposure} = (DFR * TC * WR * AR * MAF * DA) / BW * 1000$$

Where:

- DFR = Dislodgeable foliar residues (μg/cm^2 per kg a.s./ha)
- TC = Transfer coefficient [a]: 220 cm^2/hr for adults and 120 cm^2/hr for children 6 < 11 years old
- WR = Working rate (For non-professional use indoor a working rate of 1 hours/day for adults and 0.5 hours for children 6 < 11 years old are assumed)
- AR = Application Rate (kg a.s./ha)
- MAF= Multiple application factor
- DA = Dermal absorption (%)
- BW = Body weight (60 kg)

[a]: Transfer coefficients were derived representing activities for indoor plants using the study measuring exposure while pruning ornamental citrus trees (US EPA SOP 2012).

For the resident post application direct exposure resulting from accidental entry into treated plants no specific methodology was identified that would allow to address adult and child dermal, and child oral (hand to mouth) exposure in indoor location. To assess the dermal exposure for adults and child, the above-mentioned formula, used for worker exposure assessment in case of professional use of PPPs outdoor (EFSA 2014), can be employed using transfer coefficient specific for indoor settings, as worst case, and with a

15-minute exposure (derived from assessment of professional PPP; EFSA 2022). No specific model was retrieved to assess accidental post application direct exposure of child *via* the oral route resulting from hand to mouth behaviour after touching treated indoor plants. In the absence of specific transfer coefficient values for this indoor scenario the model proposed to assess this exposure scenario in the outdoor location (modified from Martin et al 2008; see above) could be considered sufficiently conservative for the in indoor location.

Given the peculiarity of PPPs as compared to the use of BPs indoor, a number of exposure determinants, specifically related to the application of a product on plants, that characterize the resident and the bystander exposure in the indoor environment are lacking. Actually, in the exposure assessment of BPs models to assess post application exposure for resident and bystander are available and highly differentiated to cover several product types. However, what is lacking are:

- drift values for specific product type PPP application on indoor plants (drift values indoor for trigger spray, pre-pressurised aerosol can and manually pressurized sprayer);
- treated area (green/glass house and room apartment) or number of plants.

For the indoor location also the greenhouse application is relevant especially for northern Europe.
There is therefore the need to characterize this scenario and the related parameters, specifically: average dimensions, types (open, closed, ventilation) and types of plants.

To cover these data gaps an open literature search analysis was performed (see section **Error! Reference source not found.**).

3.6 Open literature search results for indoor scenario data gaps

Detailed results of the open literature to fill the data gaps for the non-professional indoor use of pesticides search are shown in Table 10.

Table 10 : Open literature search for indoor scenario data gaps

	Search string	**SCOPUS** document results	**Included/Not considered**

1	**TITLE-ABS-KEY** (drift) AND (pesticide) OR ("plant protection product") AND (indoor) OR (house) AND ("non professional") OR (amateur)	26	**Not considered.** When screening the search results, it was observed that the reference to residential exposure was related mostly to exposure of residents in agricultural areas and not due to use of PPPs by non-professionals.
2	**ALL** (drift) OR **ALL** (deposit) AND **TITLE-ABS-KEY** ("plant protection product") OR **TITLE-ABS-KEY** (pesticide) AND **ALL** (indoor) OR **ALL** (house) AND **ALL (** "non professional") OR **ALL** (amateur)	6	**Not considered**. When screening the search results, it was observed that the reference is not related to use of PPPs by non-professionals indoor.
3	**ALL** (drift) OR **ALL** ("drift deposit") AND **TITLE-ABS-KEY** ("plant protection product") OR **TITLE-ABS-KEY** (pesticide) AND **ALL** (indoor) OR **ALL** (house)	**500**	5 **considered** for relevance check.
4	**ALL** (drift) OR **ALL** ("drift deposit") AND **TITLE-ABS-KEY** ("plant protection product") OR **TITLE-ABS-KEY** (pesticide) AND **ALL** (indoor) OR **ALL** (house) AND **ALL** (amateur) OR **ALL** ("non-professional")	4	**Not considered.** When screening the search results, it was observed that the reference related to exposure of residents in agricultural areas and not due to use of PPPs by non-professionals.
5	**ALL** (drift) OR **ALL** ("drift deposit") AND **TITLE-ABS-KEY** ("plant protection product") OR **TITLE-ABS-KEY** (pesticide) AND **ALL** (greenhouse) AND **ALL** (amateur) OR **ALL** ("non-professional")	6	**Not considered.** When screening the search results, it was observed that these were mainly related to professional use of PPPs.
6	**ALL** ("area treated") OR **ALL** ("plant pot") AND **TITLE-ABS-KEY** ("plant protection product") OR **TITLE-ABS-KEY** (pesticide) AND **ALL** (indoor) OR **ALL** (house)	10	**Not considered.** Results are out of scope.
7	**TITLE-ABS-KEY** (pot) OR **TITLE-ABS-KEY** ("area treated") OR **TITLE-ABS-KEY** ("plant pot") AND **TITLE-ABS-KEY** (indoor) OR **TITLE-ABS-KEY** (house)	1505	**Not considered.** Results are out of topic.
8	**ALL** ("spray application") AND **ALL** (drift) AND **ALL** (indoor) AND **ALL** ("plant protection product") OR ALL (pesticide))	49	**Not considered.** When screening the search results, it was observed that these were mainly related to professional use outdoor of PPPs.
9	**ALL** ("spray application") AND **ALL** (drift) AND **ALL** (greenhouse) OR **ALL** (glasshouse) AND **ALL** (pesticide) OR **TITLE-ABS-KEY** ("plant protection product")	228	3 **considered** for relevance check.
10	**TITLE-ABS-KEY** (pot) OR **TITLE-ABS-KEY** ("area treated") OR **TITLE-ABS-KEY** ("plant pot") AND **TITLE-ABS-KEY** (indoor) OR **TITLE-ABS-KEY** (house) AND **TITLE-ABS-KEY** (number)	328	**Not considered.** Results are out of topic.

11	**ALL** (glasshouse) OR **ALL** (greenhouse) AND **ALL** (dimension) AND **ALL** (ventilation) AND **ALL** (amateur) OR **ALL** ("non-professional"))	5	**Not considered.** Results are out of topic.
	TOTAL (before relevance check)	8	Before duplicate check
		7	After excluding duplicates
	TOTAL (after relevance check)	**0**	Excluding those not relevant to exposure indoor even from the title & abstract/full text screening.

Drift values indoor for trigger spray and pre-pressurised aerosol can

Overall, 7 references have been identified as potentially relevant to non-professional use of pesticides indoor and exposure data/methodologies. Following a relevance check *via* screening the abstract/full text, none of the references have been considered as relevant to the specific search objective.

The results are mainly related to:

- Professional use of PPP in outdoor location.
- Transfer of pesticides from the workplace to the home (para-occupational or take-home exposure)
- Health effects associated with non-occupational pesticide exposure in rural areas.

Area treated indoor and number of plants indoor

No references have been identified. Results are out of topic.

Greenhouses specific parameters (dimension, type of ventilation)

No references have been identified. Results are out of topic.

Overall, based on the retrieved open literature, it is concluded that there are no data available related to "drift values indoor for trigger spray and pre-pressurised aerosol can", "the area treated indoor and number of plant indoor" and "greenhouses specific parameters".

3.7 Surveys' Results

3.7.1 Non-professional user surveys

Specialised sellers (UNIMI - Italy)

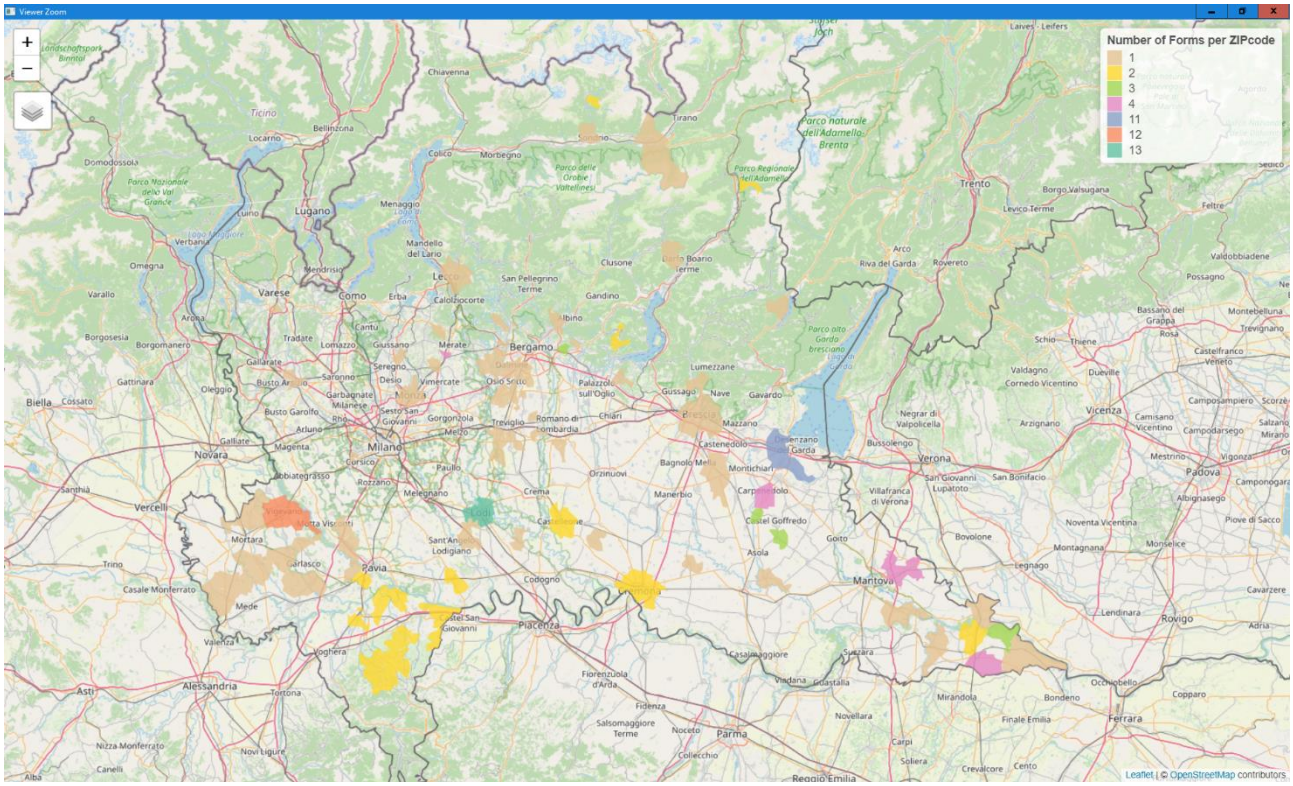
A total of 146 persons compiled the questionnaire. Of these, 139 apply PPPs. The number of compiled digital and paper questionnaires are 35 and 111, respectively. It is noted that not all individuals that indicated to use PPPs replied to all questions of the survey. In order

to facilitate the interpretation of the survey outcome results are discussed following a logic sequence of questions and not reflecting the numerical sequence of questions. The graphical output of the results can be found in Annex A.

The geographical distribution of the sellers participating in forecasting the survey, is outlined in the following GIS Map (Figure 2). The location of the seller is based on the ZIP code (Q4).

The completed questionnaires come from several regional provinces: Milano, Lodi, Brescia, Mantova, Cremona, Bergamo, Varese, Sondrio and Pavia. The different colours represent the number of participants (increasing number from light brown to green).

Figure 2: Geographical distribution of retailers based on Zip codes



Personal Data

Most of participants (95%; N=139) attending agricultural sellers use PPPs (Chart Q1, Annex A).

The age (from 30 to > 60) and the gender of the participants are fairly equally distributed unlike to educational level for which a higher representation of secondary school diplomas (60%), when compared to primary school level (14%) and university level, is registered (26%) (Chart Q2, Q3, and Q5, Annex A).

Type of plant protection products/Tool used

Types of pesticides

In Q6 chart (Annex A) the range of different categories of PPPs used is presented (total answers = 137). Insecticides (40%; N=107) represent the most purchased PPPs, followed by herbicides (25%; N=67) and fungicides (22%; N=59), and by snail killers (13%; N=35).

The results presented in Q7 (total answers = 136) chart (Annex A) shows that, among the respondents, advice from sellers is asked always by approximately 10% (N=13), occasionally by 61% (N=83), often by 7% (N=10) of users, while, about 22% (N=30) always know what they need to buy/apply.

Types of PPPs

Regarding the types of products (total answers = 136), liquids to dilute (44%; N=82) and or ready to use liquid (37%; N=69) are preferred compared to solids ready-to-use (11%; N=20) and/or solids that need to be diluted (9%; N=17) (Chart Q8, Annex A).

Environments

The PPPs applied by the respondents (total answers = 137) are mainly used for treatment of ornamental and vegetable garden (30%; N=74 and 22%; N=53, respectively), followed by lawn (16%; N=40), plants on balcony (15%; N=37). Orchards (10%; N=25), plants indoor/in house (4%; N=9) and green house (3%; N=6) are the types of plants/crops less treated (Chart Q9, Annex A).

Time spent applying and frequency of application

For all environments considered, except for orchards, the majority of non-professional users have stated to spend less than 5 minutes /day applying PPPs. In orchards the majority of users indicated a use ranging from 5 to 30 minutes. For certain environments (lawn, N=6; orchard, N=4; ornamentals garden, N=2; vegetable, N=4 garden; greenhouse, N=1) a use of more than 30 minutes was reported (see chart Q10). Among these, only 4 individuals specified to apply for up 2 hours, in lawn and orchards (Chart Q22, Annex A).

For all the environments, except for indoor, the majority indicated a seasonal or monthly use followed by a weekly use. Only few records were reported for a daily use; on ornamentals located in balconies or garden and in vegetable garden (Chart Q11, Annex A).

Equipment used

Regarding the equipment used to apply PPPs (total answers = 136), respondents generally apply RTU nebulizer spray (26%; N=49), followed by backpack pressurized dispenser (up

to 25L) with lance (17%; N=32), pressurized dispenser with launce (3 to 6L) (13%; N=25), spray can (14%; N= 26), hand pressurized spray (spray dilution to be prepared) (12%; N= 22) and nebulizer (spray dilution to be prepared) (9%; N= 17)(Chart Q12, Annex A).

A similar trend was observed for the equipment frequency of use, although only 26 individuals answered to this question. Higher frequency was indicated for RTU nebulizer spray, nebulizer (spray dilution to be prepared) and backpack pressurized dispenser (up to 25 L) with lance (from 20 to 27%). The use of spray can, pressurized dispenser with launce (3 to 6L) and hand pressurized spray (spray dilution to be prepared) are less frequently used (approximately <10% each) (Chart Q12b, Annex A).

Amount of PPP applied

The amounts of PPPs used are generally low (total answers = 87). RTU spray are applied for 1 to 5 min by the 20% (N= 20) of respondents, less than 1 minute for 26% (N=25) of respondents and more than 5 minutes by 8% (N= 8) of respondents. For solutions to be prepared, 31% (N= 30) indicated to use one measuring cup (liquid or solid), 6% (N= 6) one drinking cup (approx. 200 ml) and 4% (N=4) use half of the product container (approx. 500 ml) (Chart Q23, Annex A).

Re-entering

About half of the respondents (N= 129) don't re-enter the lawn or garden within 24 h after treatment (Chart Q21, Annex A).

Personal protective equipment (PPE)

Although non-professional PPPs Italian label do not provide indications regarding the use of personal protective equipment (PPE), only a minor number of the respondents (total answers = 137) (8%; N=19) indicated to apply PPPs without the use of any protection. As single device, users of PPEs preferred wearing gardening gloves (26%; N=65) followed by face mask (20%; N=50), work wear (18%; N=46) and eye protection (goggles) (11%; N=27) (Chart Q13, Annex A). Anyway, the majority reported use of more than one PPE (Chart Q 13b, Annex A).

Indoor

According to Q14-Q15 (Annex A), 52 (41%) individuals stated to use PPPs on small/medium plants (total answers = 126), while 21 (19%) on big (high) plants (total answers = 108). For both pots sizes the majority indicated to apply on 1 to 5 pots. Seventeen respondents indicated to apply on both small/medium and high plants. These results are in contrast with the results obtained from Q9, according to which, only 11 individuals indicated to use PPPs indoor/in house. It seems that, despite not having selected the indoor use option (Chart Q9, Annex A), some participants apply PPP on indoor small, medium and/or big plants.

Nearly all refer to care to keep person/children and pets away from areas where PPP is applied (Chart Q16, Annex A).

Greenhouse

The results show that only a small proportion of participants (total answers = 140) has a greenhouse (6%; N=8). Among these, only six individuals indicated the greenhouse size; 3 cabin size (approx. 5-15 m^2), 1 large table size (approx. 2m^2), 1 outdoor house size (between 15-35 m^2) and 1 a vegetable garden size (>35 m^2). The majority of greenhouses have a door and a window (Charts Q17-Q19, Annex A).

Vegetable garden surface

A vegetable garden surface of more than 35 m^2 was indicated by 54% (N=38) (total answers 70), between 10 and 35 m^2 by 24% (N=17) and less than 10 m^2 by 21% (N=15) of respondents. About half of the total participants don't have a vegetable garden (Chart Q20, Annex A).

Consumer panel (RIVM - Netherlands)

The results are given per product group and grouped on that level. This means that percentages are given to each response that cover all the available subtypes within that group. It is known that for example a weed killer is available as spray products, ready-to-use products or a concentrate requiring dilution. Implicitly, this means that the total number of responders for a specific product is lower than for the product group. As a consequence, the response per product group such as a 'weed killer' can be diffuse, but perhaps quite uniform for specific subtypes such as for a 'ready-to-use weed killer spray' as the directions for use as often similar for that subtype. In the analysis of the raw data the result has been stratified into the product subtypes to see if a typical use can be derived from the results. The results and typical uses will be discussed in the results section below.

The results of the survey are divided into group results about residential settings and product use. Here, the reader will find the summary results. The report only presents the overall results and not the stratified result to gender, age or educational level. The graphical output of the results can be found in Annex B.

The survey started with 583 persons. 78 were removed due to the exclusion criterion "not running your own household" (see B3, Annex B). Of 505 responders to the survey, 293 indicated to be non-users (see B4, Annex B). 211 responders (42%) did use PPPs in and around the house. Per category of products this resulted in the following (see B4, Annex B):

- Weed killers: n = 94 responders (19%)
- slimicides: n = 80 responders (16%)
- insecticides: n = 94 responders (19%)

- algae, fungi, moss removers: n = 62 responders (12%)
- lawn treatment products to tackle moss and weeds: n = 34 responders (7%)
- other: n = 9 responders (2%)

These high-level results indicate that some responders use multiple PPPs. The sample size is considered to be adequate to derive generic behaviour within the population. Due to some granularity in the subtypes of products the *n* per product subtype is lower than reported above. For example, a weed killer can be used as a ready to use spray product, but also as concentrate that needs to be diluted before it is poured over the weed.

Personal data

Residential setting

The percentages below are based on n = 211 unless stated otherwise for the types of greenhouses the responders have. The residential settings are presented below by topic.

Presence and re-entering others

In 67% of the situations, no other persons are present during use. Twenty six present of the responders indicated that adults are present during use and 7% indicated that children are present (see B5, Annex B). Of the respondents, 63% indicated that others did not re-enter the area after 24 hours after application and 29% replied that others did re-enter the area within 24 hours (see B6, Annex B).

Type of home

Most responders live in a terraced house (40%), in a detached house (15%), semi-detached house (14%), corner house (14%), an apartment (10%) or other (see B7, Annex B).

Small and medium size plants

Most responders have 1 to 5 small to medium sized plants (44%), followed by 6 to 10 plants (20%) and by none (14%). Eleven and 10% reported to have 11 to 15 and more than 15 plants, respectively (see B8, Annex B).

Large plants

Most responders have 1 to 5 large sized plants (55%), followed by none (19%) and 6 to 10 plants (15%) (see B9, Annex B).

Garden surface

The garden surfaces of the responders seemed to be rather uniformly distributed with surface areas between 10-100 m2 (three answer groups are merged, (10-35; 35-50; 50-

100), each approximately 20%) making up about 60% of the responses. Only 5% did not have a garden or vegetable garden (see B10, Annex B).

Greenhouse

About 14% of the responders stated to have a greenhouse (n = 41) that are either small table models or of the size of a small shed (see B11). Most of those greenhouses have open airways (22%) or windows (19%). Quite a lot of greenhouses contain a lid, which is almost directly correlated to the small table sized models (see B12, Annex B).

Weed killer

Of the users of PPPs 19% indicated that they use weed killers (see B4, Annex B). The underlying percentages are based on n = 94, with the exception of the answers about how much time mixing and loading takes for a product (n = 33) as not all product need mixing and loading.

Location and type of weed killer typically used

Weed killers are most of all applied in the garden, *i.e.,* 80%. The lawn or balcony was selected by 17% and 10% of the responders (note multiple answers were possible). Only 4% used the products in their vegetable garden. Indoor use (not including greenhouses) of products was also selected by few (4%) (see B13, Annex B). Approximately 30% use a ready-to-use trigger spray to apply the product. Other popular product subtypes are ready-to-use powders, granules or tablets (16%), ready-to-use aerosol cans (11%) or concentrates that require dilution into a spray device be it a normal trigger (3%) or pump spray (11%) or a larger carry-on or moveable pump spray (13%) (see B14, Annex B). All subtypes are most of all applied in the garden, on the lawn are also used ready-to-use powder tablets or granules, ready-to-use trigger spray and concentrates that are diluted in a larger carry-on or moveable pump spray and on the balcony are also used ready-to-use powder tablets or granules, aerosol cans, ready-to-use liquid and concentrates that require dilution in a pump spray are also used (see B15, Annex B).

Frequency and duration of application of a weed killer

According to the results the main use of weed killers is on a regular basis during the season, almost 50% indicated. Monthly use was mentioned by 24%, followed by yearly and weekly, *i.e.* 14% and 10% respectively (see B16, Annex B). Looking further at the subtypes, a ready-to-use trigger spray and concentrates diluted into a spray device is mainly used on a regular basis during the season, whereas ready-to-use powders, granules or tablets is mainly used on a monthly basis (see B18).

Weed killers are mostly used between 10 to 30 minutes (46%), followed by 5 to 10 minutes (35%), more than 30 minutes (10%) and up to 5 minutes (8%) (see B17, Annex B). When a ready-to-use trigger spray and concentrates that are diluted in a larger carry-on or moveable pump spray are used, it takes in majority of the time between 10 to 30 minutes

and when concentrates that require dilution into a normal trigger or pump spray are used, it takes in majority of the time between 5 to 10 minutes. Ready-to-use powders, granules or tablets are used between 10 to 30 minutes as often as 5 to 10 minutes (see B19, Annex B). The duration of use does not seem to be dependent of the frequency of use as from a first glance there does not seem to be a correlation between duration of use and frequency of use (see B20, Annex B). Also, it does not seem that individuals with larger gardens use the products longer (see B21, Annex B).

Amount of weed killer applied

The amounts used of ready-to-use liquids or concentrates are generally small, *i.e.* that of a cap (24%) up to the size of a drinking glass (17%). In case of spraying, it was indicated that it lasts about 1 to 5 minutes (16%) or even longer than 5 minutes (16%) (see B22, Annex B). It is noted that the duration of spraying is an indicator for the amount applied and not for the total time performing the task. The larger pump sprays (5L and more) take longer to use. The amount does not seem to correlate with the size of (vegetable) garden (see B23, Annex B). In case the product requires mixing and loading (n=33), the preparation of a dilution from a concentrate takes in most cases 1 to 5 minutes (68%) (see B24, Annex B).

Personal protective equipment during application of weed killer

People using the weed killer say in 43% of the responses that they use gloves, but another 43% indicates not using any protection at all. Other protective gear such as clothing, respiratory protection and/or goggles were mentioned by very few responders (respectively 8%, 13% and 6%) (see B25, Annex B).

Descriptions provided can be seen as overall typical use for the whole product category and to some extent for each subtype product. The small number of respondents per subtype product does not make it possible to derive correlations from the results. Based on the results on whole product category it seems there is no correlation between duration of use and frequency of use. Also, the size of the (vegetable)garden does not seem to correlate with the application time and with the amount used.

Slimicides

Of the users of PPPs 16% indicated that they use slimicides (see B4, Annex B). The underlying percentages are based on n = 80, with the exception of the answers about how much time mixing and loading takes for a product (n = 6) as not all product need mixing and loading.

Location and type of slimicide typically used

Slimicides are almost exclusively used in the garden (86%), vegetable garden (22%) and to a little extend on the lawn (8%) (see B26, Annex B). Over 80% of the product subtypes

are ready-to-use powders, granules or tablets. Trigger sprays and aerosol cans are used as well, but the share is very small (both 3%) (see B27, Annex B).

Frequency and duration application of slimicides

Responders indicated that slimicides are used seasonally (57%), monthly (17%) and yearly (13%). None of the responders used the product on a daily basis (see B29, Annex B). The duration of use is typically shorter than 5 minutes (54%), 5 to 10 minutes (30%) or longer than 10 minutes (12%) (see B30, Annex B). As ready-to-use powders, granules or tablets is the most used subtype, the percentages are mainly based on its results (see B31-B32, Annex B). At first glance it seems that individuals who use the product monthly uses the product longer (5 to 10 minutes) then individuals who uses the product seasonally (shorter than 5 minutes) (see B33, Annex B). Further there seems to be a correlation between individuals with larger gardens and the duration of use (see B34, Annex B).

Amount of slimicides applied

For the amount of granules (most responders indicated that the product is made of granules) that is used per time, the options cap/spoon (21%), drinking glass (14%), and free text option (21%) were selected in most cases (see B35, Annex B). In the free text field, the responders explained that they sprinkle directly from pack or a single or couple of hands full depending on the number of plants they wish to protect.

Only three individuals responded that mixing and loading is required. Preparing dilutions from a concentrate takes in all cases 1 to 5 minutes (see B37, Annex B).

Personal protective equipment during application of slimicides

People using the slimicides say in 32% of the responses that they use gloves, but 56% indicates not using any protection at all. Other protective gear such as clothing, respiratory protection and/or goggles were mentioned by very few responders (see B38, Annex B).

Insecticides (lice, moths, other pests)

Of the users of PPPs 19% indicated that they use insecticides (see B4, Annex B). The underlying percentages are based on n = 94, with the exception of the answers about how much time mixing and loading takes for a product (n = 14) as not all product need mixing and loading.

Location and type of insecticides typically used

The various insecticides are mainly used outside in the garden (65%) and on the balcony (15%). Interestingly these products are used indoors by a large percentage, i.e. 25% (see B39, Annex B). Most popular are the ready-to-use products either as trigger spray (31%), aerosol can (27%) and as powder, granule and tablet (22%) (see B40, Annex B). Where trigger sprays and powders, granules and tables are mostly used in the garden, aerosol cans are also used indoors (see B41, Annex B).

Frequency and duration of application of insecticides

Seasonal use was selected the most, followed by monthly and yearly, i.e. 32, 22, and 22% respectively. Weekly use was also relatively high as 14% indicated a weekly use (see B42, Annex B). By type of application, ready-to-use trigger spray are mainly used seasonally and yearly, whereas aerosol cans are used seasonally, monthly, yearly and weekly. Ready-to-use powder, granules or tables are mainly used seasonally and monthly (see B44, Annex B). The duration of use is typically less than 30 minutes and in most case below 5 minutes (37%). Five to 10 minutes and 10 to 30 minutes was indicated by 35 and 23% of the responders (see B43, Annex B). There seems to be no correlation between the duration of use and the frequency of use (see B46, Annex B). Also the size of the (vegetable)garden does not seems to correlate with the duration of use. Up to 5 minutes was mostly indicated by responders with a garden size of 1 to 35 m^2 and 50 to 100 m^2, whereas responders with a garden size of 35 to 50 m^2 indicated to use a product 5 to 10 minutes (see B47, Annex B).

Amount of insecticides applied

On the day of use, spraying takes up to one minute (27%) or five minutes (28%) (see B48, Annex B). The time of spraying does not seems to correlate with the size of the (vegetable) garden (see B49, Annex B). The fact that there is no correlation with garden size can be explained by the targeted control of, for example lice, which often occur on certain plants. In case a product requires mixing and loading (n = 14), preparing dilutions from a concentrate takes in most cases 1 to 5 minutes (45%) of less than a minute (29%) (see B50, Annex B).

Personal protective equipment during application of insecticides

People using the slimicide say in 35% of the responses that they use gloves, but 48% indicates not using any protection at all. Sixteen percent uses a simple respiratory mask (see B51, Annex B).

Moss, algae, fungi removal

Of the users of PPPs 12% indicated that they use treatment against moss, algae, fungi on pavement (see B4, Annex B). The underlying percentages are based on n = 62, with the exception of the answers about how much time mixing and loading takes for a product (n= 21) as not all product need mixing and loading.

Location and type of moss, algae, fungi removal typically used

Products used to remove moss, algae and fungi are used most often outdoors in the garden (74%), on the lawn (22%) and balcony (20%) and to some extend also indoors (11%). The responders who selected other used the products on the driveway or parking spot (paved areas) (see B52, Annex B). The product subtypes is quite divers and almost evenly distributed across the ready-to-use spray products or powder, granules, tablets (13 to

20%) and the diluted products used in pump sprays be it the smaller (flacon) (14%) or larger (rideable) ones (10%) (see B53, Annex B). Also looking at the locations where the subtypes are used, it is divers. Indoors, aerosol cans are usually used, and on the lawn mainly powder, tablets or granules. For the diluted products used in pump sprays there were no difference where they were applied (see B54, Annex B).

Frequency and duration of application of moss, algae, fungi removal

Seasonal use was selected the most, followed by yearly and monthly, i.e. 46, 23, and 16% respectively. Weekly use was also relatively high as 13% indicated a weekly use (see B55, Annex B). The duration of use was higher than seen for the other PPPs questioned in this survey with the most selection range of 10 to 30 minutes (42%) followed by more than 30 minutes (29%) and 5 to 10 minutes (24%) (see B56, Annex B). There seems to be no pattern between the type of application and the frequency and duration of use (see B57-59, Annex B). There is no correlation between the size of (vegetable) garden and de duration of use (see B60, Annex B). This is not surprising as the responders had to indicate the size of the (vegetable) garden excluding pavement, where treatment of moss, algae, fungi removal is used as well.

Amount of moss, algae, fungi removal applied

The amount used per application when spraying a ready to use product was in most case more than 5 minutes (24%), followed by 1 to 5 minutes or less than a minute (20 and 11% respectively). Twelve percent of the responders indicated that they used half a bottle per event (see B61, Annex B). The time spraying did not seem to be correlated with the size of a (vegetable) garden but that is to be expected as of moss, algae, fungi removal applied are used on terrace or pavement (see B62, Annex B).

In case a product required mixing and loading, it generally takes 1 to 5 minutes according to 71% of the responders (n = 21) using such product. Again, it is noted that for these products a relatively large part of the responders indicated a relatively long duration, in this case for diluting the product, i.e. 12% indicated that it takes more than 5 minutes (see B63, Annex B).

Personal protective equipment during application of moss, algae, fungi removal

Regarding protection it is indicated that gloves are used by 42%, but working clothes, respiratory masks, and goggles are worn by 15, 14, and 14% respectively. 41% did not use any protective gear (see B64, Annex B).

Lawn treatment products

Of the users of PPPs 7% indicated that they use lawn treatment products to tackle moss and weeds (see B4, Annex B). The underlying percentages are based on n = 34, with the exception of the answers about how much time mixing and loading takes for a product (n = 4) as not all product need mixing and loading.

Location and type of lawn treatment product typically used

Not surprisingly, most lawn treatment products are used on the lawn (62%), with the remainder being used in the garden (30%), balcony (14%) and in the greenhouse (8%) (see B65, Annex B). Also 6% uses the lawn treatment product indoors, this are only aerosol cans (see B67). Most of the products are ready-to-use powders, granules or tablets (50%) or ready-to-use bottles (25%) that can be poured (see B66, Annex B).

Frequency and duration of application of lawn treatment products

Use is predominantly during the season (45%), monthly (21%) or yearly (15%) (see B68, Annex B). Per event, the responders indicate that they require 10 to 30 minutes (42%), 5 to 10 minutes (32%) or less than 5 minutes (15%). Still 9% indicate that it may take more than 30 minutes (see B69, Annex B). The frequency and duration of use does not seem to be related to the application type (see B70-B72, Annex B). The duration of use for a (vegetable) garden with size of 50 to 100 m^2 seems to be shorter than for a (vegetable) garden size of more than 100 m^2 (see B73, Annex B).

Amount of lawn treatment products applied

Use amounts are either relatively small (cap; 21%) or relatively large (half a bottle; 17%). If it is applied by spray, it is generally longer than 5 minutes (14%) or between 1 to 5 minutes (11%) (see B74, Annex B). There seems to be no correlation between amount used and the size of the (vegetable) garden (see B75, Annex B). In case a product need mixing and loading (n=4), the dilution process is said to take between 1 to 5 minutes by most responders (66%) or even longer than 5 minutes (17%) (see B76, Annex B).

Personal equipment during application of lawn treatment products

The responders use quite some protective gear when applying lawn treatment products of which 40% mentioned gloves, 25% respiratory masks, 14% goggles and 13% work clothing. 33% said not to wear protective gear (see B77, Annex B).

3.7.2 Authority Surveys

The outcome of the survey among the Authorities for each question is summarised below, while a graphical presentation of the results along with more details when necessary are presented in the Annex C – Authorities survey – Results.

Areas of risk assessment involved (Question 1)

Seven (7) out of the fourteen (14) authorities, *i.e.,* 50% of those responded to the questionnaire, are involved only in the risk assessment of PPPs. The rest seven (7) authorities (50%) are also involved at least in the risk assessment of biocides.

Three (3) authorities (21% of total responders) are involved in the risk assessment of all PPPs, Biocides and REACH chemicals, while one (1) authority (7% of total responders) is additionally involved in the risk assessment of cosmetics (Chart C.0, Annex C).

Restrictions not related to exposure/risk assessment (Question 2)

All fourteen (14) MSs answered that there are restrictions regarding the hazardous classification of a PPP in order to be authorized for non-professional use. The restrictions concern physical, health and environmental hazards.

In eleven (11) out of the fourteen (14) responding MSs, corresponding to 79% of total responders, restrictions are set regarding the physical hazards of the PPPs on some or all hazard classes, while in three (3) MSs (21%) there is no restriction related to physical hazards for the authorisation of a PPP (Chart C.1.0, Annex C).

In all fourteen MSs that responded to the survey there are restrictions regarding the health hazards and the relevant classification of PPPs. Although these restrictions are highly variable, none of the responding MS permits the authorisation of a PPP for non-professional use, when at least one of the following hazard classes applies:

- Acute Tox. 1 or Acute Tox. 2; H300 Fatal if swallowed
- Acute Tox. 1 or Acute Tox. 2; H310 Fatal in contact with skin
- Acute Tox. 1 or Acute Tox. 2; H330 Fatal if inhaled

The above were indicated in addition to the hazard classes

- Muta. 1; H340 May cause genetic defects
- Carc. 1; H350 May cause cancer
- Repr. 1; H360 May damage fertility or the unborn child

which are among the exclusion criteria in accordance with Regulation (EC) 1107/2009 leading to no authorization of PPPs even for professional users.

It is noted that although no PPP available in the market is expected to be classified as Muta 1, Carc. 1 and Repr 1, these hazard classes are included in the restrictions in place at national level.

In twelve (12) out of the fourteen (14) responding MSs PPPs for non-professional use should also not be classified as CMR Cat. 2. Classification for adverse effects on or *via* lactation is a restriction to eight (8) responding MSs (Chart C.1.1, Annex C).

Regarding the acute toxicity endpoints, there are also restrictions for PPPs classified as Acute Tox. 3 (all exposure routes) in thirteen (13) of the responding MSs. The classification in Acute Tox. 4 Category is a restriction for authorization for PPPs for non-professional users in two (2) MSs when it concerns oral exposure and in three (3) MSs when it concerns dermal and inhalation exposure routes (Chart C.1.2, Annex C).

There are also restrictions related to classification as Resp. Tox. And Skin Corr. 1 (in 11 out of 14 responding MSs), Skin Sens.1 (in 7 out of 14 responding MSs) and Eye Dam. 1 (in 9 out of 14 responding MSs). Only in two (2) responding MSs classification as Eye Irrit. 2 of a PPP is a reason for non-authorization for non-professionals, while classification as Skin Irrit. 2 is a restriction on one (1) responding MS (Chart C.1.3, Annex C).

Regarding classification of PPPs for specific target organ toxicity, there are restrictions in eleven (11) out of the fourteen (14) responding MSs when classification concerns Category 1 both in case of single and repeated exposure (STOT SE 1 and STOT RE 1). Ten (10) of the responding MSs apply restrictions also for classification in the respective Category 2 (STOT SE 2 and STOT RE 2). Classification for respiratory irritation (STOT SE 3) and for drowsiness or dizziness (STOT SE 3) is a restriction in five (5) and (6) MSs, respectively (Chart C.1.4, Annex C).

In twelve (12) out of the fourteen (14) responding MSs in this survey, corresponding to 86% of total responders, there are no restrictions for environmental hazards, while the remaining two (2) MSs, (14% of total responders) that have relevant restrictions, do not allow the authorisation of a product classified for environmental hazard at any hazard class (either aquatic acute or chronic toxicity) (see Annex C, Chart C.1.5).

The restrictions regarding the classification for physical hazards varies significantly among the responding MSs, however, only three (3) out of the fourteen (14) responders apply no relevant restriction. Nine (9) MSs do not allow the non-professional use of PPPs when they are classified as explosives, while in more than (6) MSs restrictions concern classification as flammable (solid, gas or liquid), oxidising gas or self-reactive substances and mixtures/organic peroxides (Chart C.1.6, Annex C).

Exposure assessment tools/models used (Question 3)

AMATEUR USER (see Annex C, Chart C.2.1)

Ten (10) out of the fourteen (14) MSs that participated in the survey, *i.e.* 71%, accept the UK predictive exposure model (UK POEM) Amateur/home garden user exposure models to assess the exposure of a non-professional user handling a PPE, *i.e.*

- *AEROSOL SPACE TREATMENT MODEL (Spraying - air space spraying Model 1, TNsG)*
- *AEROSOL SURFACE TREATMENT MODEL (Consumer product spraying and dusting Model 2, TNsG)*
- *TRIGGER SPRAY SURFACE TREATMENT MODEL (Consumer product spraying and dusting Model 2, TNsG)*

-DUSTABLE POWDERS – PUFFER PACK MODEL (Consumer product spraying and dusting Model 2, TNsG)

The German Model (Home and allotment garden area) is considered acceptable by seven (7) out of fourteen (14) MSs (50%), while six (6) MSs (43%) responded that they accept the UK predictive user exposure model (UK POEM) - [Home garden sprayer (5 litre tank)].

Six (6) out of fourteen (14) MSs (43%) answered that they accept the exposure assessment of an non-professional user with to the EFSA Guidance (EFSA AOEM, EFSA Opex), by selecting hand-held application scenario. Two (2) of them specified that the "potential exposure" is considered.

Moreover, in case of non-professional use in greenhouses, three (3) out of fourteen (14) MSs (21%) use the Dutch model.

Other models are considered acceptable as well, by a smaller number of MSs: two (2) MSs (14%) use the Garden exposure model (UPJ model), two (2) MSs (14%) use the PHED model, one (1) MS (7%) use the Subsoil treatment model 2 TNsG part 2, (p 177) and another (1) MS (7%) use the Consumer product painting model 2 (biocides, TNsG, 2002) in case of brush painting application.

One (1) MS (7%) referred to the Guidance document on work-sharing in the northern zone in the authorisation of PPPs; Version 10.0; June 2021. According to this GD, for a non-professional user the following exposure models are acceptable: UK POEM, German model (75th percentile), Dutch model (greenhouses), PHED, Puffer pack model, UK Trigger Spray model.

Finally, three (3) out of fourteen (14) MSs (21%) use a combination of the tools and methods described in the "*Non-professional use in home gardens-exposure assessment*" Version 1.3 (2022-03-22) approved by the Interzonal Steering Committee (iZSC). One (1) of them provided more information regarding the approach followed, by citing the specific evaluation models for the different scenarios examined:

- SCENARIO 1 "family garden" & SCENARIO 2 "vegetable garden and orchard"
  - Evaluation models: "*Non-professional use in home gardens - exposure assessment, version 1.3 (2022/03/22) Tables 2, 3 and 4*"

Regarding scenario 1"family garden", exposure can be refined taking into account the percentage of the garden area occupied by the various crops specified in the national model of "family garden".

- SCENARIO 3 "vineyard and olive grove" & SCENARIO 4 "cereal"
  - Evaluation models: AOEM1 (Manual hand-held) - AOEM1 (Manual knapsack) EFSA Model (Manual hand-held)
- SCENARIO 5 "use in apartment"
  - The approach adopted takes into account the ECHA methodology for the assessment of human health exposure to biocides.

BYSTANDER/RESIDENT (Chart C.2.2, Annex C)

The majority of the MSs that participated in the survey [nine (9) out of fourteen (14), *i.e.* 64%] use the EFSA Guidance to assess the bystander/resident exposure in case of non-professional application of a PPP, at least as a first Tier assessment tool.

Fewer MSs referred to other models as well. More specifically, three (3) out of fourteen (14) MSs (21% of total number of responders) consider acceptable the German Guidance - Martin *et al.*, (2008) – Home and allotment garden area (HG). One (1) out of these three MSs (7% of the total responders) considers also the *Operator exposure guidance for amateur (home garden) pesticides* (by CRD).

One (1) out of fourteen (14) MSs (7%) referred to the methodology described in the working document '*Non-professional use in home gardens-exposure assessment*'. According to this, the EFSA Guidance can be used to assess the bystander/resident exposure, but specific data are used for surface deposits in home gardens and allotment gardens. Additionally, in this working document the following are stated: *"Spray drift data for hand-held equipment is not available but the comparison of data for surface deposits from professional uses and uses in home garden and allotment gardens in DE show that drift will be lower in most of the cases. In addition, the default vapour concentrations from the EFSA guidance were obtained for large treated fields. However, entry into treated crops is assumed to be similar for professional and non-professional uses"*.

One (1) out of fourteen (14) MSs (7%) answered that the bystander/resident exposure is considered covered by the operator exposure and therefore, no separate assessment is performed.

Finally, one (1) MS, in order to address this question, referred to the Guidance document on work-sharing in the northern zone in the authorisation of PPPs; Version 10.0; June 2021. According to this GD, the EFSA Calculator is used for the resident exposure assessment as Tier I. For tunnel uses, the EFSA calculator outdoor scenario should be used as it is considered the worst-case bystander and resident exposure scenario.

Non-dietary exposure assessment: National requirements / National/Zonal Guidance Documents (Questions 4,5 and 6)

All fourteen (14) MSs that participated in the survey stated that there are in place either national requirements regarding the parameters to be used in the non-dietary exposure assessment for PPPs to be authorised for non-professional use (11 in total) or they follow the relevant zonal/interzonal guidance document (two and one MSs, respectively).

Eleven (11) out of the fourteen (14) MSs that participated in the survey stated that they consider also the *Working document: Non professional use in homegardens* [*izSC Item 07a_Working Document Non professional use in home gardens_Version 1.3_2022-03-*

22.pdf; https://circabc.europa.eu/ui/group/0b40948d-7247-4819-bbf9-ecca3250d893/library/1cc132c9-6756-4481-9f41-aabd96377c29/details], developed by DE (BfR) and discussed within the Interzonal Steering Committee, for the exposure assessment at product authorization level.

Based on the retrieved information, it is evident that the guidance in place in different MSs varies from only restrictions to hazard classification and packaging requirements to specific instructions related to the intended uses (crops and application equipment) or the specific exposure assessment tools/models to be used.

More details regarding the information provided in relation to the available National Guidance documents are presented in Annex C – Authorities survey – Results.

Non-dietary exposure assessment: maximum task duration (Question 7)

Based on the survey responses, the reported maximum duration considered in the non-dietary exposure assessment for non-professional users of PPPs, ranged between half (0.5) to two (2) hours with the majority of the MSs (57% of total number of responders) considering 2 hours. It was explicitly noted, though, that for some formulation/application types, for which a specific model is available, shorter time periods are considered as well e.g. 144 sec [default value set in UK predictive exposure model (UK POEM) Amateur/home garden for aerosols]. In addition, one MS noted that no maximum duration is considered in general, while another one stated that one (1) hour is taken into account as a Tier 1 assessment (Chart C.3, Annex C).

Non-dietary exposure assessment: maximum treated area (Question 8)

With respect to the maximum treated area considered, a rather divided situation is apparent where, five (5) MSs (36% of total number of responders) answered 0.05 ha (500 m^2) ,while another five (5) reported 0.1 ha (36% of total number of responders) with one (1) MS making a link to the packaging size. More specifically it was noted that packaging of PPPs for nonprofessional use can maximally correspond to a treated area of 0.1 ha, while in cases where the risk assessment is acceptable only for a smaller area than 0.1 ha, then a restriction is applied to packaging (Chart C.4, Annex C).

Two (2) MSs (14% of total number of responders) consider one (1) ha as the relevant treated area for PPPs to be applied by non-professionals, while one (1) MS noted that no maximum area is considered in general. Finally, one (1) MS responded that the maximum area depends on the scenario assessed and according to their national requirements it ranges between 0.05 ha for gardens and orchards to 0.5 ha for vineyards and olive groves.

Non-dietary exposure assessment: relevance of greenhouse uses (Question 9)

Twelve (12) out of the fourteen (14) MSs, 86% of total number of responders, stated that greenhouse uses are also assessed in case of PPPs for non-professional users.

When MSs were asked to specify the type of greenhouse considered in their assessments, no clear responses were provided, with only one (1) MS noting that the Mediterranean type is accepted as a minimum requirement.

Four (4) MSs (28% of total number of responders) answered that the Dutch Greenhouse model is used for the estimation of the "operator" exposure levels.

One (1) MS noted that the models currently used for the assessment of occupational exposure are also recommended in their national guidelines for the non-professionals, applying an exposure reduction factor that takes into account the differences in the surface area treated. For non-professional greenhouses, the default value of 35 m^2 indicated in the guidance document "*Non-professional use in home gardens - exposure assessment, version 1.3 (2022/03/22)*" is applied.

Additionally, one (1) MS responded that the GH AOEM is used as a worst-case approach, considering the manual knapsack scenario and the results for potential exposure.

One (1) MS noted that indoor uses are assessed as outdoor ones, unless specific models are available, while another one specified that the scenarios assessed refer to manual applications only considering a treated area of 0.1 ha.

Finally, it is noted that four (4) out of the twelve (12) MSs that answered positively that greenhouse uses are assessed also for non-professionals, did not provide any further detail or information regarding the approaches followed at national level.

Non-dietary exposure assessment: relevant application equipment (Question 10)

Among the fourteen (14) MSs that participated in the survey, thirteen (13) answered that non-professionals can apply a PPP with sprayers (either ready-to-use or for spray solution prepared by adding water) and spray cans. Eleven (11) MSs answered that a PPP for non-professional use can be applied also *via* a hand-pressurized spray (spray solution to be prepared by adding water). Eight (8) out of fourteen (14) MSs consider the use of backpack pressurized dispenser with lance (up to 25 litres). Similarly, eight (8) MSs accept the use of pressurized dispenser with lance (3 to 6 litres). Twelve (12) MSs consider acceptable the application with watering can. One (1) MS considers also the use of fogging machine and another (1) MS the use of paint brush. Manual lance connected to tank is considered relevant by one (1) MS (Chart C.5, Annex C).

Some MSs referred to specific requirements for granular PPPs. More specifically, two (2) out of fourteen (14) MSs consider application by hand, while one (1) of them considers also push along spreaders, hand operated spreading equipment and shaker packs relevant for PPPs to be used by non-professionals. Finally, one (1) MS reported that if the risk assessment for a specific equipment cannot be covered by the Working Document "*Non-professional use in home gardens - exposure assessment*, version 1.3 (2022/03/22)", the applicant must submit a suitable model.

Non-dietary exposure assessment: acceptability of personal protective equipment (PPE) (Question 11)

Nine (9) out of the fourteen (14) MSs that participated in the survey (64% of total responders) do not consider acceptable the use of any personal protective equipment (PPE) during handling a PPP for non-professional use (Chart C.6, Annex C).

All five (5) MSs (36% of total responders) that consider the use of PPE for refining the operator exposure estimates for non-professionals, accepts the use of gloves as a risk mitigation measure. Three (3) out of five (5) MSs accepting the use of PPE, stated that the use of work clothing (long-sleeved shirt, long trousers) is considered acceptable for refining the exposure even in case of PPPs for non-professional use, with one MS adding also "sturdy footwear". One (1) MS, however, stated that for the estimation of the exposure of a non-professional user, the "potential exposure" is considered, e.g. when using the EFSA Calculator.

It should be noted that the question concerned the PPE that is acceptable for refining the non-dietary exposure of non-professionals. However, some MSs referred also to more general considerations related to PPE used based on hazardous properties. More specifically, one (1) MS stated that the use of respiratory protection (dust mask P3/FFP3) is acceptable in case of PPPs containing microorganism, since they are considered as potential sensitisers. One (1) MS accepts also the use of eye/face protection in case the P280 precautionary statement is triggered as a result of classification with H319.

Non-dietary exposure assessment: relevance of post-application (re-entry) activities (Question 12)

All fourteen (14) MSs that answered the survey stated that setting a re-entry period as a potential risk mitigation measure is not considered acceptable.

Regarding the worker exposure to be conducted, there was one (1) MS specifically stating that according to the definition laid down in the respective EFSA Guidance (2014 and 2022), workers, are persons who, as part of their employment, enter an area that has been treated previously with a PPP or who handle a crop that has been treated with a PPP. In consequence, workers should be considered professionals that can re-enter in a garden after the treatment (being the garden treated by a non-professional user) to perform their task. It is recognised, however, that the exposure is limited, due the application method, the treated area, *etc*, and thus a shorter exposure duration may be considered.

4 Conclusion and discussion

4.1 Literature search and data gap analysis

From the results of the present project activities, it can be concluded that a reasonable number of models and approaches were identified to assess the exposure in residential settings scenarios of the user, "user re-entry", resident and bystander as individuals that are directly or indirectly exposed to PPPs in the outdoor location. In comparison with products authorized in Italy, the Netherlands and Greece, the available models cover an adequate range of product types, formulations, applications to low- or high-level targets, tasks, and default values. No exposure data were retrieved to assess the exposure during the application of weed wiping products, however, the exposure during this type of application could be considered covered by spray application with same or higher application rate. Overall, no substantial data gaps were identified for non-dietary exposure assessment of non-professional use of PPPs in outdoor location.

For the indoor location, it is possible to conclude that the available data and methodologies are adequate to assess the exposure of the user that prepares and/or applies the products and no substantial data gaps were identified. No guidance documents or methodologies specific for the bystander exposure assessment were retrieved. Although, methodologies and exposure models are available for the exposure assessment of the resident in indoor locations, data gaps were identified for exposure determinants that are specifically related to the use of PPPs. These include specific drift values for PPP application on indoor plants (trigger spray, pre-pressurised aerosol can and manually pressurised sprayer) and default values for treated area or number of plants treated.

No specific model(s) or exposure data for the greenhouse exposure scenario in residential setting were found. The exposure assessment for the greenhouse scenario can be performed using professional models assuming reduced surfaces (e.g., 10 to 50 m^2). For this scenario the exposure is estimated for the user during mixing and loading (if needed), the application and re-entry activities. Bystanders are unlikely to be present during application. Residents (adult and child) exposure should be considered, but probably only for the entry into treated crops.

4.2 Non-professional user surveys

Generic use of PPP by non-professional users in Italy

From the results of the survey delivered through specialized sellers in Italy, it can be concluded that a large proportion of non-professional users are aware of the way PPPs should be managed and handle the product with gloves at least. Nearly all refer to keep person/children and pets away from areas where PPP is applied. Insecticides and herbicides are most frequently used in vegetable and ornamental gardens. Regarding the

types of products, liquids to be diluted and/or RTU liquids are preferred over RTU solids or solids that need to be diluted.

The preferred equipment used to apply PPPs is the RTU nebulizer spray, followed by backpack pressurized dispenser with lance, pressurized dispenser with launce (approx. 3 to 6 litres) and spray can, hand pressurized spray (spray dilution to be prepared) and nebulizer (spray dilution to be prepared).

The amounts of PPPs applied are generally small. RTU spray are applied for 1 to 5 min by the 20%, less than 1 minute by 26% and more than 5 minutes by 8% of respondents. For solutions to be prepared, 31% indicated to use one measuring cup (liquid or solid), 6% one drinking cup (approx. 200 ml) and 4% use half of the product container (approx. 500 ml). The majority indicated a seasonal or monthly use followed by a weekly use in outdoor locations. Only few records were reported for a daily use; on ornamentals located in balconies or garden and in vegetable garden.

About half of the respondents don't re-enter the lawn or garden within 24 h after treatment.

About half of the respondents indicated to apply PPPs on both small and high potted plants located indoor, the majority of which on 1 to 5 pots.

Only few participants indicated to have a greenhouse (6%; N=8). Not all of these provided answers on greenhouse size or on its ventilation. Among respondents, the majority indicated a greenhouse size less than 15 m^2 with ventilation (door and/or window, or open passage).

It should be noted that the results of questionnaire disclosed in Italy was limited to Lombardia region. It was not feasible within the framework of the present project to deliver the questionnaire to specialized sellers at national level. Although this single region cannot be considered representative of the whole nation, the results are well balanced for age, gender and educational level of the participants. Anyhow, it is of note that the results of the Italian survey in terms of types of products, amount applied, time and use frequency, are similar to those of the Netherland survey which was conducted on a statistically representative sample of the population (see below).

Generic use of PPP by non-professional users in the Netherlands

From the results of the Dutch survey among non-professional users, it can be concluded that weed killer, slimicides, insecticides and treatment against moss, algae, fungi on pavement are most commonly used in the garden. Lawn treatment products are mainly used on lawn. Insecticides, treatment against moss, algae, fungi on pavement and lawn treatment product are also used indoors by non-professionals. The fact that products for the treatment against moss, algae and fungi on pavement are also used indoors may be explained by the treatment of walls and ceilings. Indoors, aerosol cans are mainly used. Further, ready-to-use products are most commonly used, followed by concentrate that

needs to be diluted. Powder, tablets or granules are subtypes that are almost never used except for slimicides.

Non-professional users mainly apply PPPs during growth season with at least weekly use.

The amounts of treatment against moss, algae and fungi and lawn treatment are generally more than the amounts of weed killer, slimicides and insecticides. The most selected option for the duration of spraying with treatment against moss, algae and fungi and lawn treatment is more than 5 minutes while for weed killers, both options are chosen 1 to 5 min and more than 5 minutes. Insecticides are sprayed 1 to 5 minutes or less than 1 minute.

For solutions to be prepared, again the amount of treatment of moss, algae or fungi and lawn treatment is highest, half bottle (about 500 ml) or whole bottle while for weed killers and insecticides, most responders reported using one measuring cap/cup or spoon or one drinking cup (about 200 ml). The amounts of slimicides used are mainly a handful or spoon of ready-to-use powder, granules and tablets.

Half of the non-professional users wear no protective equipment while using PPPs and the other half handle PPPs with gloves as the main PPE. A quarter of those (?) who use lawn treatment products reported wearing respiratory protection (mask) during use.

When non-professional users apply PPP, in most situations there are no bystanders, sometimes adults or children are present.

Few participants reported having a greenhouse (14%; n=41). Among the respondents, the majority indicated that they have a greenhouse in the form of small table models (about 1 m^2) or the size of a small shed (5 to 15 m^2). Most small table models have a lid and most small shed sized greenhouses have a door and windows that open.

About half of the respondents have 1 to 5 plants in their home and/or balcony, about one-fifth have 6 to 10 plants and some respondents reported having more than 11 plants. These can be small to medium or large plants. In addition, about one-fifth of the respondents indicated that they had no plants in their home or balcony.

The results of the survey disclosed in the Netherlands was fairly homogeneous with regard to age and gender. It can be concluded that the category of PPPs used is also equally divided, except for lawn treatment products which was used by smaller percentage of the responders. It should be noted that the results provided can be seen as general typical usage for the whole product category and to some extent for each sub-type of product. Due to the small number of respondents per product subtype, only an indication of possible correlations can be given.

The surveys in Italy and the Netherlands show many similarities, but also show some differences. The use of slimicides appears to be a little bit higher in the Netherlands compared to Italy. It could be related to regional differences having more snails in the

Netherlands, prompting the need for such products. Also, it is noticed that use indoors and in greenhouses is higher in the Netherlands, which could be explained by the regional climate. Use outdoors in Italy seems to be focused more on ornamentals and vegetables that require more space (larger gardens) and more use outdoors. Although not directly clear from the surveys, one might have expected a difference in seasonal use or frequency as the growth season may be longer in Italy compared to the Netherlands. It could be that the way the questions were posed that it would not lead to differences between the countries. Moreover, even if growth season would be longer, it would not change the way a product is used or how the exposure would be assessed.

Even though there are differences in where products are used (in terms of country) and the type of products, it does not seem to influence how the products are used as shown above. If the application area increases, it oftentimes means that the application form changes to means with higher application rates. Hence the required time to do a task is not changed significantly.

4.3 Authority survey

Regarding the survey conducted among the Member States and in particular, among the Competent Authorities responsible for the evaluation of Plant Protection Products, a rather high number of MSs provided their feedback (fourteen). All responding MSs welcomed the initiative of conducting a survey to collect the different approaches followed in the area of non-dietary exposure to PPPs for non-professional use. The need to have a guidance was stressed, acknowledging, however, the national requirements that may be in place already.

It has been apparent that hazard-based restrictions for the authorization of the products are applied in the different EU countries. Although these restrictions are highly variable, some specific hazard classes are taken into account by all MSs *i.e.,* Acute Tox 1 & 2, Muta. 1, Repr. 1 & Carc. 1.

With respect to the models/tools used for the exposure assessment of the non-professional user, the majority of the MSs apply the UK POEM (amateur/home-garden), the German model (home and allotment garden area) and the EFSA calculator for the manual scenario. Nonetheless, other models/approaches have also been mentioned, including some used in other regulatory frameworks e.g., in biocides. For the variables that affect exposure such as the maximum task duration, the majority of the MSs consider 2 hrs while, for the maximum area treated, a rather divided situation is apparent where either 0.05 ha or 0.1 ha is taken into account, reflecting the requirements that apply in each country.

The most relevant application equipment for non-professional use according to MSs, are the ready-to-use sprayers and spray cans. Hand-pressurized sprayers or backpack pressurized dispensers with lances have been reported while, watering cans were also considered relevant by a high number of responders.

For the bystander/resident exposure assessment, the German Guidance-Martin *et. al.*, (2008) is considered rather obsolete by the majority of the MSs, that apply instead the EFSA Guidance and calculator. However, a small number of MSs (3 out of 14 responded in the survey) still accepts the German Guidance.

Apart from the outdoor uses, the MSs consider also the greenhouse uses as relevant for the non-dietary exposure assessment for non-professionals. However, little can be deduced with respect to the type of greenhouse considered since almost none of the MSs provided an answer. With regard to the models used, there is no clear outcome due to limited feedback. Nonetheless, the Dutch Greenhouse model is used by four MSs, while other MSs assess the indoor uses in the same manner as they do for the outdoor ones.

The majority of the MSs do not accept the use of PPE for refining the exposure assessment although, a small number considers gloves as a potential risk mitigation measure. The issue of PPE was also related to the hazardous properties of the product. In that case, some MSs accept the use of respiratory protection (dust mask P3/FFP3) for PPPs containing microorganism, since they are considered as potential sensitisers while, eye/face protection is accepted in case the P280 precautionary statement is triggered as a result of classification with H319.

For all MSs the setting of a re-entry period as a potential risk mitigation measure is not considered acceptable.

The implementation of this project was characterized by a strong multidisciplinary component. While PPPs and BPs authorized for professional use may differ significantly in terms of the application equipment used and the parameters considered in the exposure assessment, many of the exposure scenarios for non-professional users of PPPs and for other potentially exposed actors have points in common with biocides. In this respect, and since the consortium consisted of experts with specific knowledge in risk and exposure assessment of pesticides and/or biocides, the exchange of experience and knowledge was required when the first steps of the project implementation were taken. For instance, the first phases of the project required an effort to align the "language" used in the two areas of expertise and identify any differences in terminology. Subsequently, the transfer and exchange of specific knowledge allowed to manage any challenges and build the capacities to define scenarios and factors characterizing exposure related to non-professional PPPs use. Among the results of this project perhaps, the first is to have created a consortium that has developed and reinforced the skills and knowledge to face the future challenges of risk assessment for non-dietary non-professional exposure of PPPs. The above-mentioned challenges should be considered for the further steps to be taken in the development of an EU guidance document regarding the non-dietary exposure assessment to PPPs for non-professional use.

5 Recommendations

Following the conclusions drafted above it shows that already a lot of valuable information is available to risk assessors to determine the exposure to PPPs by non-professionals. The information is mainly derived from the PPP framework describing outdoor scenarios and from the Biocides framework for the indoor scenarios. The list of available models from the PPP and Biocides framework is quite long. They can be used for a range of products available to the non-professional. To pinpoint exactly which model is preferred and what exposure determinants to apply, other than those already set as defaults in the models, is subject to further study. It is recommended to have workshops (with representatives from across the EU and from PPP and BP frameworks similar to this consortium) to determine the preferred models or approaches for specific products and exposure scenarios, indicating which values may be fixed and which values may be overwritten on a case-by-case situation. In that recommended exercise it would be beneficial if the preferred models and defaults could be derived at a specific product and exposure scenario level, similar to those specified in the surveys aimed at the non-professional. While doing so, the newly gathered information from the surveys may be reason to make changes to already existing defaults. The basis for those defaults may not always be derived for non-professional use of PPPs and therefore its quality and appropriateness is improved if derived from data on the target population. A simple step to make changes on product use information from the surveys is to evaluate where they differ from use instructions given by product manufacturers.

Ultimately, the aim is to acquire a harmonized approach on how to assess the exposure in a standardized way. An additional layer to this step of harmonisation is taking account of regional differences if so needed. Based on the three surveys it does appear that regional differences exist, but not always impacting on how the product is being used by non-professionals. Quite a lot of similarities were observed in case the same type of product was questioned about in the surveys in Italy and The Netherlands. Differences were seen in cases where the target of treatment is different (e.g., more snails compared to insects) or the dimensions differ (larger fruit gardens in Italy). In general, it simply means that a different application type is selected by the non-professional as the tasks involves larger surface areas for example. To obtain a broader view of non-professional use across the EU, more surveys could be performed in for example Northern, Central and East Europe. Its focus should be more on identifying regional differences and product types rather than product application as the latter is typically prescribed by the manufacturer of the product.

Standardisation of models and defaults can also help aligning the Member States in addressing product approval. While some differences are policy driven, like accepting PPEs, most of the differences seem to be based on preferences for certain models. Some are even developed 'in-house' within MS resulting in the 'German', 'Dutch' and 'UK' models. Initiatives like the EFSA calculator help in harmonizing and standardizing the approach in risk assessments, but still much is to be gained from further collaborations; like the collaboration in this present work by the consortium. Creating and drafting the models and underlying defaults is just the first step, maintenance and support need to be accounted for as well. Establishing a working group to support from a scientific point of view may ensure that this niche in the PPP risk assessment is covered.

The identified data gaps on exposure determinant of use of PPPs indoors and in greenhouses could not be completely covered by the survey data. This means that the data gaps still need to be addressed. Although the latter does not appear to be a major use amongst PPP, due to its confined space may be a scenario where briefly high exposure via inhalation may arise. Alternatively, the exposure assessments for florists and the Greenhouse model designed for occupational settings could serve as starting points for exposure assessments. Extrapolation to non-professional users may focus on those situations where higher exposures, likely briefly, can arise.

6 Dissemination plans

The activities, results and recommendations of the present project will be promoted and communicated to reach out multiple audiences, directly or indirectly, potentially interested in the project activities, such as peers in the research field, industry, other commercial players, and policymakers.

Knowing that one of the main results of the project highlighted is the need of a harmonized EU approach for risk assessment and management for non-professional use of PPP, activities will be conducted to disseminate the project results at EU level, by:

- Informing national Focal Points of EFSA advisory forum;
- Attending:
    - Scientific and standing committees closely related to the non-dietary risk assessment and management of PPP;
    - Working groups aimed at implementing methodologies and guidance for non-dietary exposure assessment;
    - Member States zonal and non-zonal forums for discussion and harmonization on implementation of EU directive and regulations on pesticides active substances and PPPs.
- Informing the ad hoc working group on human exposure to biocides (HEAdhoc; ECHA).

Besides disseminating the project outcomes and raising awareness for the identified data gaps for exposure assessment, these actions aim to gather evidence on the priority of EU programming in implementing a harmonized regulatory approach (zonal, non-zonal) for non-dietary risk assessment of non-professional PPPs.

In addition to the above activities, the project outcome will be disseminated in congresses and scientific societies, at national and international level, to reach a scientific audience close to the non-dietary exposure of non-professional PPPs.

7 References

Biocides Human Health Exposure Methodology v 1.0 (2015). http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/workinggroups/human-exposure.

Bremmer HJ; Blom WM; van Hoeven-Arentzen PH; Prud'Homme de Lodder LCH; van Raaij MTM; Straetmans EHFM; van Veen MP; van Engelen JGM. Pest Control Products Fact Sheet. To assess the risks for the consumer. Updated version for ConsExpo 4. RIVM report 320005002/2006. https://www.rivm.nl/bibliotheek/rapporten/613340003.pdf.

Prud'homme de Lodder LCH, Bremmer HJ, Pelgrom SMGJ, Park MVDZ, van Engelen JGM. Disinfectant Products Fact Sheet. To assess the risks for the consumer. RIVM report 320005003/2006. https://www.rivm.nl/bibliotheek/rapporten/320005003.pdf.

Martin S, Westphal D, Erdtmann-Vourliotis M, Dechet F, Schulze-Rosario C, Stauber F, Wicke H and Chester G, 2008. Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application Journal für Verbraucherschutz und Lebensmittelsicherheit, 3, 272–281.

EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P, Martin S, Sanvido O, Chiusolo A, Colas M and Istace F, 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. https://doi.org/10.2903/j.efsa.2022.7032

Guidance document on work-sharing in the northern zone in the authorization of plant protection products (Version 10.0; June 2021

HEEG opinion: Default human factor values for use in exposure assessments for biocidal products. http://echa.europa.eu/documents/10162/19680902/heeg_opinion_17_default_human_factor_values_en.pdf

HEEG opinion: Exposure model Primary exposure scenario – washing out of a brush which has been used to apply a paint. https://echa.europa.eu/documents/10162/1060554/heeg_opinion_11_washing_out_of_a_brush_en.pdf/7e6436c4-9f84-4174-b9ed-324e02b0cac6?t=1388670047902.

TNsG (Technical Notes for Guidance), 2002. Human exposure to biocidal products. Guidance on exposure estimation. 409 pp. Available online::http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg+human+exposure+2002_en.pdf

TNsG (Technical Notes for Guidance), 2007. Human exposure to biocidal products. 102 pp. Available online:

http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg-human-exposure-2007_ en.pdf

UPJ (Union des Entreprises pour La Protection des Jardins), Data on amateur exposure to pesticides. Unpublished

US EPA (US Environmental Protection Agency), Health Effects Division Office of Pesticide Programs (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment (available at: http://www.epa.gov/opp00001/science/USEPA-OPP-HED_Residential%20SOPs_ Oct2012.pdf) 582 pp.

US EPA (US Environmental Protection Agency), 2012. Science Advisory Council for Exposure, policy number 3, revised March, 2012, agricultural transfer coefficients. Office of Pesticide Programs, Health Effects Division, Washington, DC, USA. 123 pp.

US EPA (US Environmental Protection Agency), 2001. Science Advisory Council for Exposure, policy number 12, recommended revisions to the standard operating procedures (SOPs) for residential exposure assessments. Office of Pesticide Programs, Health Effects Division, Washington, DC, USA.

CRD (The Chemical Regulation Directorate, UK). OPERATOR EXPOSURE GUIDANCE FOR AMATEUR (HOME GARDEN) PESTICIDES. Available online: https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/amateur-use-guidance.doc

Dutch exposure model (greenhouses), 1992. Dutch authorities. Unpublished report

PSD (Pesticide Safety Directorate). Bystander exposure guidance.Reissued 2008. Available online: http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/B/Bystander- exposure-guidance.pdf

PHED (Pesticide Handlers Exposure Database), 1992. US Environmental Protection Agency, Health and Welfare Canada, National Agricultural Chemicals Association, Vesar Inc., Springfield, IL, USA.

Rautmann D, Streloke M and Winkler R, 2001. New drift values in the authorisation procedure for plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft (Federal Biological Research Center for Agriculture and Forestry), 383, Berlin, Germany, 133–141.

izSC Item 07a_Working Document Non professional use in home gardens_Version 1.3_2022-03-22.pdf; https://circabc.europa.eu/ui/group/0b40948d-7247-4819-bbf9-ecca3250d893/library/1cc132c9-6756-4481-9f41-aabd96377c29/details

Glossary / Abbreviations:

ACV	Airborne Concentration of Vapour
AGES	Austrian Agency for Health and Food Safety
AL	Ready-to-use liquid
AOEM	Agriculture Operator Exposure Model
AR	Application Rate
BfR	German Federal Institute for Risk Assessment
BP	Biocide Product
BPI	Benaki Phytopathological Institute
BVL	German Federal Office of Consumer Protection and Food Safety
BW	Body weight
CRD	Chemical Registration Division
CTGB	Dutch Board for the Authorisation of Plant Protection Products and Biocides
D	Drift
DA	Dermal Absorption
DEFRA	Department for Environment, Food and Rural Affairs
DFR	Dislodgeable foliar residue
EFSA	European Food Safety Authority
EGEL	Estimated Gardener Exposure Level
EU	European Union
EW	Emulsion, oil in water
Freq	Frequency hand to mouth
GD	Guidance Document
GIS	Global Information System
GR	Granule
H	Exposure duration
HCHH	Hugh Crop Hand Held
HEADhoc	Ad hoc Working Group on Human Exposure

HEEG	Human Exposure Expert Group
HG	Home and allotment garden
HSE	Health Safety Executive
HSL	Health and Safety Laboratory
IA	Inhalation Absorption
IgR	Ingestion Rate for Mouthing of Grass/Day
iZSC	Interzonal Steering Committee
LCHH	Low Crop Hand Held
M&L	Mixing and Loading
MAF	Multiple Application Factor
MS	Member State
OA	Oral Absorption
POEM	Predictive Operator Exposure Model
PPE	Personal Protective Equipment
PPP	Plant Protection Product
QR	Quick Response
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	Dutch National Institute for Public Health and the Environment
RTU	Ready-To-Use
SA	Surface area of hands
SDEB	Systemic Exposure of Bystanders via the Dermal Route
SDER	Systemic Dermal Exposure Resident
SE	Saliva extraction factor
SG	Water-soluble granule
SIEB	Systemic Inhalation Exposure Bystander
SIER	Systemic Inhalation Exposure Resident
SOEH	Systemic Oral exposure Hand to Mouth
SOEO	Systemic oral exposure object to mouth

SOP	Standard Operating Procedure
T	Time
TC	Transfer Coefficient
TNsG	Technical Notes for Guidance
TTR	Turf Transferable Residue
UBA	German Environmetal Protection Agency
UK	United Kingdom
UNIMI	Università degli Studi di Milano
UPJ	Union des Entreprises pour la Protection des Jardins et des Espaces Publics
US EPA	United States Environmental Protection Agency
WDG	Water dispersible granules
WG	Water soluble of dispersible granules
WP	Wettable Powder
WSB	Water Soluble Bag

Appendix A – List of Biocide product types and exposure scenario potentially relevant to assess non-professional exposure to PPPs

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
2	Non-Professional pond treatment	Powder	ConsExpo 4.1, default scenario for mixing and loading of Pest Control Product, powder It is noted that: 1) Detailed information for the used of this default database is presented in the Pest Control Product Fact Sheet (RIVM report 320005002/2006). However, no additional information is included on mixing and loading only. 2) This mixing and loading model only consists of dermal exposure data.	Dermal exposure: Exposed area: 820 cm^2 (HEEG opinion 17 - Default human factor values for use in exposure assessments for biocidal products) Contact rate of 0.033 mg/min and release duration of 79.8 seconds are defaults of this ConsExpo 4.1 model.	
3	Animal house disinfection by spraying	Liquid	Dermal exposure: – Spraying Model 2, TNsG 2002 – Spraying Models 2 and 3, TNsG 2002 – Spraying Model 7, TNsG 2002 – Spraying Model	Dermal exposure: – Indicative values Spraying Model 2: Hands (actual) 7.8 mg/min; hands (potential) 273 mg/min; body 222 mg/min – Indicative values	For assessing dermal exposure to an active substance, Spraying Model 7 was chosen which is not reflected in the TNsG User Guidance. Assessment of inhalation

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
			9, TNsG 2002 – ConsExpo 4.1 Dermal model: Direct dermal contact with product: constant rate <u>Inhalation exposure:</u> – Spraying Model 2, TNsG 2002 – Spraying Models 2 and 3, TNsG 2002 – Spraying Model 9, TNsG 2002 – ConsExpo 4.1	Spraying Model 3: Hands in gloves 2.04 mg/min; body 250 mg/min – Values Spraying Model 7: 75th 100 mg/min – Indicative values Spraying Model 9: Hands 2300 mg/min; body 4900 mg/min – Parameters ConsExpo 4.1: • Exposed area: 1,75 m^2 • Contact rate: 540 mg/min • Release duration: 400 min <u>Inhalation exposure:</u> – Indicative value Spraying Model 2: 76 mg/m3 – Indicative value Spraying Model 3: 17.3 mg/m3 – Indicative value Spraying Model 9: 3600 mg/m3	<u>exposure</u> by Member States: Frequencies and durations: 1 h, 2 h 6 times per year, 126 min once per day, 180 min 12 times per year, 400 min For most actives, the Spraying Model 2 was chosen to cover inhalation and dermal exposure for the task animal house spraying. This model is based on the task "Mixing and loading liquids in reservoir for powered spray application at 4 to 7 bar pressure as a coarse or medium spray, indoors, overhead and downwards. Scenario - medium pressure spray applications, e.g. for remedial biocides". However, there is a great discrepancy in the duration and frequency of the task which might be due to different assumptions on the setting e.g. stable size, treated area, animals etc. An harmonisation in this point (if feasible) would be desirable.
6	Manual paint spraying by professional and non-professional		<u>Non-professional use:</u> ConsExpo 4.1, painting products, spray painting, pneumatic spraying	<u>Professional use:</u> Spray duration: 6 hours Non-professional use is covered by professional use.	Inhalation exposure can be disregarded: – due to large droplet size, – and/or if the vapour pressure of the substance is low. However, if the substance causes local effects in the upper respiratory tract,

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
	users (worst-case for paints, inks, polymer emulsions)		Professional use: Approach 1) BEAT "masonry preservatives" Approach 2) BEAT "designated scenario for PT 7 covers indoor decorative painting"		inhalation exposure needs to be considered. Non-professional use: The TNsG 2007 (p. 63) presents indicative exposure values for pneumatic spray paint (manual spraying: medium/coarse spray). If the flowchart of TNsG 2007 is followed, the indicative values, in case considered valid, should be used. In case considered not valid, the flowchart advices to use ConsExpo fact sheet models (Paint Products Fact Sheet, RIVM report 320104008/2007 (2007)). Professional use: There is no worked example in BEAT which describes professional spray of painting (in general). The designated scenario for PT 7 in BEAT which covers indoor decorative painting" seems the best suited "worst case" model (compared with Spray application of masonry preservative).
6	(Indoor) wall plastering by professi		Non-professional	Non-professional use: Exposed area: 1950 cm^2 (hands and forearms, HEEG opinion 17 -	Inhalation exposure is not considered by the model ConsExpo default scenario for wall plastering.

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
	onal and non-professional users (worst-case for use in construction materials)		use: ConsExpo 4.1 Do-It-Yourself Products Fact Sheet, RIVM report 320104007/2007 (2007), plaster/equalizer, wall plaster	Default human factor values for use in exposure assessments for biocidal products) Exposure duration: 120 minutes (default ConsExpo 4.1)	For outdoor wall plastering consumers, use the Consumer Brush Painting model 3.
18	Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals	Powder	Approach 2) Hand-held flexible Duster (TNsG 2007 p. 63) (consumer) Approach 3) ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application for dusting of powder (consumers)	Approach 1) Application duration for pouring is 1 hour (Excel Database human exposure, scenario "gush dilution on surface" for solid substances). A factor 100 is used for the indicative (potential) exposure value (HEEG Opinion on the assessment of potential & actual hand exposure 2008). Approach 2) The model from the TNsG 2007 is derived from the following simulated volunteer study: Includes crack and crevice treatment for ants in a kitchen (skirting, shelves,	Non-professional use: Approach 2 is better because it is based on TNsG 2007, while ConsExpo fact sheet is based on TNsG 2002. In case the application is not performed with hand held flexible duster/hand-held canister, but with a spoon, the inhalation exposure may be assumed negligible compared to the dermal exposure. Dusters are used to generate dust, while spoons are used because they limit dust formation. The value 2.73 (for hand/foreaem) and 2.74 (for legs/feet/face) is assumed to be the worst case, but there is no other data/model available.

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				horizontal laminate floors) using a fine powder (45% of particles less than 75 □m) and broadcast flea treatment (carpet) using coarse granules (95% of particles greater than 180 □m). <u>Indicative dermal exposure:</u> Hand/forearm: 2.73 mg/min Legs/feet/face: 2.74 mg/min. <u>Indicative inhalation exposure:</u> Inhalation exposure: 2.47 mg/m3 TNsG 2002 Consumer product Spraying and dusting Model 2: 75 □m: – Hand and forearm: 2.83 mg/min (75th percentile) – Legs/feet/face: 2.15 mg/min (75th percentile) 180 □m: – Hand and forearm: 2.5 mg/min (maximum value) – Legs/feet/face: 3.2	

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
				mg/min (maximum value) <u>Approach 3)</u> ConsExpo 4.1, scenario Pest Control Products, Dusting Powders, Application. (dermal/inhalation defaults consumer = dermal/inhalation defaults professional Note: For professionals, the defaults for frequency, spray duration and release duration need to be adapted to worker situation. The worker may use the product longer, more frequently and apply larger amounts)	
18	Non-professional use of insecticide cassettes		ConsExpo 4.1, constant surface evaporation model – Langmuir model in case little is known about the product Thibodeaux's model for emission on water based liquids.	The following specific default values should be filled in: • Applied amount: dependent on the product • Emission duration: dependent on the product • Exposure duration: 5 min • Wardrobe volume: 1.5 m3 • Ventilation rate: 0.3/hour	The model should not be used in case the concentration is very low (< 10-8 □g/L). In that case, measurements in the air should be performed. Langmuir's and Thibodeaux's methods are only required in case of the method of release by evaporation and not in the case of constant rate. See Pest Control Products

PT	Exposure scenario	state of the product (solid/ liquid/ aerosol)	Proposed exposure model	Default settings	Remarks on the proposed model
					factsheet (RIVM report 320005002/2006) for more default values.

PT: product type

Appendix B – Questionnaire used in the survey delivered to specialized sellers (UNIMI)

Q1 -Do you use plant protection products?

- Yes (go directly to the questions below)
- No (close the form)

Questions about you, the Compiler

Q2 - Age

- Less than 30 yo
- 30-40 yo
- 40-50 yo
- 50-60 yo
- More than 60 yo

Q3 - Gender

- Male
- Female
- Not Binary

GIS 1 – Municipality (Zip Code)

Q5 - Education

- Elementary

- Diploma
- University degree or more

Questions about plant protection products and your habits to use them

Q6 - What class of plant protection products do you use? (Please, if necessary indicate more than one answer)

- Herbicides
- Insecticides
- Fungicides
- Snail killer
- Others
- I do not know

Q7 - Do you ask the dealer for advice? (Please, if necessary indicate more than one answer**)**

- No, I always know what to buy / apply
- Yes
- Sometimes
- Often

Q8 - What type of plant protection products do you use? (Please, if necessary indicate more than one answer)

- Ready-to-use liquid
- Liquid to dilute
- Ready-to-use solid
- Solid to dilute

Q9 - Where do you use plant protection products? (Please, if necessary indicate more than one answer)

- Vegetable garden

- Ornamental plants in the garden
- Plants indoor/in the house
- Plants on your balcony
- Lawn
- Orchards / olive grove / wine grove / cereals
- Greenhouse

Q10 - How long (total time) does it take to apply a plant protection product (one or more plants)?

	<5 minutes	5-10 minutes	10-30 minutes	More than 30 minutes
Vegetable garden	○	○	○	○
Ornamental plants	○	○	○	○
Lawn	○	○	○	○
Orchards	○	○	○	○
In Greenhouse	○	○	○	○
Indoor	○	○	○	○

Q22 - If the maximum time taken for the daily application of a pesticide is "more than 30 minutes", please indicate the approximate time for the selected location _____

Q11 - How often do you apply plant protection products?

	Every day	3-5 times a week	Once a week	Once a mouth	Once per season	Once a year

Vegetable garden	○	○	○	○	○	○
Ornamental plants	○	○	○	○	○	○
Lawn	○	○	○	○	○	○
Orchards	○	○	○	○	○	○
In Greenhouse	○	○	○	○	○	○
Indoor	○	○	○	○	○	○

Q12 - What type of equipment do you use to apply crop protection products? (Please, if necessary indicate more than one answer and please check on the right if the equipment is your preferred one or most used)

□ Sprayer (ready-to-use) 	□ Check this option if "Sprayer (ready-to-use)" is you preferred equipment
□ Sprayer (spray solution to be prepared by adding water) 	□ Check this option if "Sprayer" is you preferred equipment

□ Hand-pressurized spray (spray solution to be prepared by adding water) 	□ Check this option if "Hand-pressurized spray" is you preferred equipment
□ Spray can 	□ Check this option if "Spray can" is you preferred equipment
□ Backpack pressurized dispenser with lance (up to 25 litres) 	□ Check this option if "Backpack pressurized dispenser with lance (up to 25 litres)" is you preferred equipment
□ Pressurized dispenser with lance (3 to 6 litres) 	□ Check this option if "Pressurized dispenser with lance (3 to 6 litres)" is you preferred equipment
□ Watering can	□ Check this option if "Watering can" is you preferred equipment

	
□ Solid ready-to-use 	□ Check this option if "Solid ready-to-use" is you preferred equipment
□ Solid Hand held  	□ Check this option if "Solid Hand held" is you preferred equipment

Q13/Q13b - Do you use PPE during application? (Please, if necessary indicate more than one answer)

- Gloves: ○ latex ○ rubber ○ gardening
- Mask
- Visor
- Eye protection equipment
- Workwear
- None

Q14 - Please, indicate the number of SMALL / MEDIUM potted plants treated with plant protection products indoor, in your house.

- None
- 1 to 5
- 6 to 15
- more than 15
- Do not know

Q15 - Please, indicate the number of HIGH potted plants treated with plant protection products indoor, in your house.

- None
- 1 to 5

- 6 to 15
- more than 15
- Do not know

Q16 - While you are applying crop protection products, is there anyone else near you indoor, in the house?

- Person
- Animal
- No

Q17 - Do you own a greenhouse?

- Yes
- No

Q18 - If yes, what is its approximate size of the greenhouse?

- Approx. 1 m^2 (Small table size)
- Approx. 2m^2 (Large table size)
- Approx. 5-15 m^2 (Cabin size)
- Between 15 and 35 m^2 (Outdoor house size)
- More than 35 m^2 (Vegetable Garden greenhouse)

Q19 - What type of opening does it have?

- A lid
- Windows that can open
- Open passage
- A door
- Door and windows

Q20 - In case you have a (vegetable) garden, what is the approximate size in square meters not including terrace or pavement?

- Less than 10 m^2
- Between 10 and 35 m^2
- More than 35 m^2

Q21 - Do you re-enter the lawn or gardening (re-potting, inspection, irrigation, harvesting) within 24 hours after treatment?

- Yes
- No

Q23 - How much do you apply each time you are using it (of ready to use or undiluted product)

- RTU spray application: ○ <1 minute ○1 to 5 minutes ○ >5 minute
- One measuring cup of liquid or powder (bottle cap as cup)
- One drinking cup (approx. 500 mL)
- I use up the whole product
- According to the manufacturer's instructions for use

Appendix C – Questionnaire used in the survey delivered to the consumer panel (RIVM)

1) What is your living situation
    a. I live with my parents or guardians (exclude from survey)
    b. I live in a household community (exclude from survey)
    c. I run my own household (alone, with partner, with partner and kids)
2) Do you use any type of official plant protection products?
    a. Weed killer
    b. Anti-snails
    c. Anti-lice and moths
    d. Algae and fungi remover
    e. Lawn protector
    f. Other
    g. None of the above
    I don't know

If any of the answers is yes, then proceed to survey. If not, the selection provides a percentage of non-users.

The second set of question relates to the use of the plant protection products and was repeated for each product type that was indicated in answering the question above.

3) Can you specify per product where you apply the product (multiple answers enabled)
    a. In the vegetable/kitchen garden or allotment
    b. In the garden
    c. On the lawn
    d. balcony

e. Indoors
f. Orchards
g. Greenhouse
h. Other
i. I don't know

4) Can you specify per each plant protection product what application type you use
   a. Ready to use product – spray
      i. Trigger spray – flacon
      ii. Aerosol spray can
   b. Ready to use product – powder, tablets or granules
   c. Ready to use product – liquid (non-refillable)
   d. Products/concentrates that require mixing with water or loading – liquid
      i. Trigger spray – flacon
      ii. Hand-pressurized/pump spray
      iii. Knapsack/rideable spray
      iv. Pressure spray
      v. Watering can
      vi. Cap of bottle as cup
   e. Products that require mixing with water or loading into a cup/spoon – powder/granule/tablet
      i. Trigger spray – flacon
      ii. Hand-pressurized/pump spray
      iii. Knapsack/rideable spray
      iv. Pressure spray
      v. Watering can
      vi. Cap of bottle as cup/spoon
5) How often do you use that product?
   a. Daily
   b. 3-5 times per week
   c. Weekly
   d. Monthly
   e. Seasonally (only during growth season with at least weekly use)
   f. Yearly
   g. other
6) How long are you using the product each time you apply it?
   a. Up to 5 minutes
   b. 5-10 minutes
   c. 10-30 minutes
   d. More than 30 minutes
   e. Other
   f. I don't know
7) How much do you apply each time you are using it (of ready to use or undiluted product)?
   a. I use a RTU spray application
      i. …Less than 1 minute
      ii. …1 to 5 minutes
      iii. …Longer than 5 minutes

b. One measuring cup of liquid or powder (bottle cap as cup)
c. One drinking glass (approx. 200 mL)
d. Halve of the bottle or product (approx. 500 mL)
e. I use up the whole product
f. Other
g. I don't know

8) If the product requires mixing and loading, how much time does that consume?
   a. Up to 1 minute
   b. Several minutes
   c. More than 5 minutes
   d. No mixing is required
   e. I don't know
9) Do you wear any type of protection?
   a. Yes, gloves
   b. Yes, working clothes
   c. Yes, respiratory masks
   d. Yes, goggles
   e. Other
   f. No
   g. I don't know

Third set of questions are about the product user in relation to their use of PPPs. Questions about their age and gender are not described here.

1) Are other people present during application?
   a. Adults
   b. Children
   c. No
   d. I don't know
2) Do you or others re-enter the lawn or work with plants (re-potting, harvest fruit) within 24 hours after treatment?
   a. Yes
   b. No
   c. I don't know
3) How many small/medium sized plants do you have (see picture for size comparison) within the house and/or balcony?
   a. None
   b. 1-5
   c. 6-10
   d. 11-15
   e. More than 15
   f. I don't know
2) How many large sized plants do you have (see picture for size comparison) within the house and/or balcony?
   a. None
   b. 1-5
   c. 6-10

d. 11-15
e. More than 15
f. I don't know

3) In case you have a (vegetable) garden, what is the approximate size in square meters not including terrace or pavement?
   a. I do not have a garden
   b. 1 – 10 m2
   c. 10-35 m2
   d. 35 – 50 m2
   e. 50 – 100 m2
   f. 100 m2 or more
   g. I don't know
4) Do you own a greenhouse? (add pictures)
   a. If yes, what is the size of the greenhouse
      i. Small table size
      ii. Large table size
      iii. Cabin size
      iv. Outdoor house size
      v. I don't know
   b. What type of opening does it have?
      i. A lid
      ii. Windows that can open
      iii. Open entry
      iv. A door
      v. Door and windows
      vi. I don't know

Appendix D – Questionnaire used in the "Authorities' survey" (BPI)

Country:

Organisation/Authority:

1. **Is the represented competent authority involved only in the risk assessment of plant protection products (PPPs)?**
   Yes ☐
   No ☐

   If no, please specify the other areas your authority is also involved in, e.g. biocides, REACH chemicals, pharmaceuticals, etc.

   Free text

2. **Are there specific restrictions regarding the hazardous classification of a PPP in order to be authorized for non-professional use?**
   Yes ☐
   No ☐

   If yes, please indicate the hazard class(es) that are not considered acceptable for PPPs to be authorised for non-professional use:

Hazard Class		Code Warning of danger		Not acceptable
Explosives	Unst. Expl.	H200	Unstable explosive	
	Expl. 1.1	H201	Explosive; mass explosion hazard	
	Expl. 1.2	H202	Explosive; severe projection hazard	
	Expl. 1.3	H203	Explosive; fire, blast or projection hazard	
		H204	Fire or projection hazard	
		H205	May mass explode in fire	
Flammable Gases	Flam. Gas 1	H220	Extremely flammable gas	
Flammable aerosols		H222 H229	Extremely flammable aerosol Pressurized container: May burst if heated	
Oxidising Gases	Ox. Gas 1	H270	May cause or intensify fire; oxidiser	
Flammable liquids	Flam. Liq. 1	H224	Extremely flammable liquid and vapour	
	Flam. Liq. 2	H225	Highly flammable liquid and vapour	
	Flam. Liq. 3	H226	Flammable liquid and vapour	
Flammable Solids	Flam. Sol. 1	H228	Flammable solid	
Self-reactive substances and mixtures Organic Peroxides	Self-react. A			
	Org. Perox. A	H240	Heating may cause an explosion	
	Self-react. B			
	Org. Perox. B	H241	Heating may cause a fire or explosion	
	Self-react. C&D			
	Org. Perox. C&D	H242	Heating may cause a fire	
		H242	Heating may cause a fire	
Acute toxicity - oral	Acute Tox. 1	H300	Fatal if swallowed	
	Acute Tox. 2			
	Acute Tox. 3	H301	Toxic if swallowed	
	Acute Tox. 4	H302	Harmful if swallowed	
Aspiration hazard	Asp. Tox.	H304	May be fatal if swallowed and enters airways	
Acute toxicity - dermal	Acute Tox. 1	H310	Fatal in contact with skin	
	Acute Tox. 2			
	Acute Tox. 3	H311	Toxic in contact with skin	
	Acute Tox. 4	H312	Harmful in contact with skin	
Skin corrosion / irritation	Skin Corr. 1	H314	Causes severe skin burns and eye damage	
	Skin Irrit. 2	H315	Causes skin irritation	
Skin sensitisation	Skin Sens. 1	H317	May cause an allergic skin reaction	
Serious eye damage / eye irritation	Eye Dam. 1	H318	Causes serious eye damage	
	Eye Irrit. 2	H319	Causes serious eye irritation	
Acute toxicity - inhalation	Acute Tox. 1	H330	Fatal if inhaled	
	Acute Tox. 2			
	Acute Tox. 3	H331	Toxic if inhaled	
	Acute Tox. 4	H332	Harmful if inhaled	
Respiratory sensitisation	Resp. Tox.	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled	

Germ cell mutagenicity	Muta. 1	H340	May cause genetic defects	
	Muta. 2	H341	Suspected of causing genetic defects	
Carcinogenicity	Carc. 1	H350	May cause cancer	
	Carc. 2	H351	Suspected of causing cancer	
Reproductive toxicity	Repr. 1	H360	May damage fertility or the unborn child	
	Repr. 2	H361	Suspected of damaging fertility or the unborn child	
	Lact.	H362	May cause harm to breast-fed children	
Specific target organ toxicity – single exposure	STOT SE 1	H370	Causes damage to organs	
	STOT SE 2	H371	May cause damage to organs	
	STOT SE 3	H335	May cause respiratory irritation	
		H336	May cause drowsiness or dizziness	
Specific target organ toxicity – repeated exposure	STOT RE 1	H372	Causes damage to organs through prolonged or repeated exposure	
	STOT RE 2	H373	May cause damage to organs through prolonged or repeated exposure	
Hazardous to the aquatic environment	Aquatic Acute 1	H400	Very toxic to aquatic life	
	Aquatic Chronic 1	H410	Very toxic to aquatic life with long lasting effects	
	Aquatic Chronic 2	H411	Toxic to aquatic life with long lasting effects	
	Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects	
	Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life	
Hazardous to the ozone layer	Chronic 3	H420	Harms public health and the environment by destroying ozone in the upper atmosphere	

Are there any other restrictions related to the approval of PPPs for non-professional use – not related to exposure/risk assessment?

Yes ☐
No ☐

Please include any reference or link.

Free text

3. **Which exposure assessment tools/models do you consider for the non-dietary exposure assessment for PPPs to be authorised for non-professional use?**
NON-PROFESSIONAL USER
   - UK predictive exposure model (UK POEM) Amateur/home garden user exposure models:

- *AEROSOL SPACE TREATMENT MODEL (Spraying - air space spraying Model 1, TNsG)*
- *AEROSOL SURFACE TREATMENT MODEL (Consumer product spraying and dusting Model 2, TNsG)*
- *TRIGGER SPRAY SURFACE TREATMENT MODEL (Consumer product spraying and dusting Model 2, TNsG)*
- *DUSTABLE POWDERS – PUFFER PACK MODEL (Consumer product spraying and dusting Model 2, TNsG)*

- UK predictive user exposure model (UK POEM) - [Home Garden sprayer (5 litre tank):
- *German Model (Home and allotment garden area)*
- *Garden exposure model (UPJ model)*
- Other – Please specify.

BYSTANDER/RESIDENT

- German Guidance - Martin *et al.,* (2008) – Home and allotment garden area (HG)
- Other – Please specify.

Free text

4. **Are there national requirements regarding the parameters to be used in the non-dietary exposure assessment for plant protection products to be authorised for non-professional use?**

Yes ☐
No ☐

5. **Do you consider the guidance provided in the *Working document: Non professional use in homegardens* [***izSC Item 07a_Working Document Non professional use in home gardens_Version 1.3_2022-03-22.pdf; https://circabc.europa.eu/ui/group/0b40948d-7247-4819-bbf9-ecca3250d893/library/1cc132c9-6756-4481-9f41-aabd96377c29/details], developed by DE (BfR) and discussed within the IzSC, for the exposure assessment at product authorization level?**

Yes ☐
No ☐

If yes, please specify which scenarios are considered.

Free text

6. **If yes, are these described in any specific documents?**

Yes ☐
No ☐

Please include any reference (preferably in English) or link.

7. **What is the maximum duration considered in the non-dietary exposure assessment for the PPP application in case of non-professional use?**

Free text

8. **What is the maximum treated area considered in the non-dietary exposure assessment of PPPs to be authorised for non-professional use?**

Free text

Please report the maximum treated area per exposure scenario if relevant.

9. **Are greenhouse uses assessed for non-professionals?**

Yes ☐
No ☐

If yes, please specify the type of greenhouse, the treated area and the type of application.

Free text

10. **Please select the equipment considered relevant for application of PPPs by non-professional users:**

- Sprayer (ready-to-use)
- Sprayer (spray solution to be prepared by adding water)
- Hand-pressurized spray (spray solution to be prepared by adding water)
- Spray can
- Backpack pressurized dispenser with lance (up to 25 litres)
- Pressurized dispenser with lance (3 to 6 litres)
- Watering can
- Small tractor
- Fogging machine
- Other – Please specify

Free text

11. Is the use of personal protective equipment (PPE) acceptable for refining the non-dietary exposure of non-professionals?

Yes ☐
No ☐

If yes, could you please specify which PPE is acceptable and which protection factor is used?
e.g. gloves, coverall

Free text

12. For post-application activities in case of non-professional use of PPPs is setting a re-entry period a potential risk mitigation measure?

Yes ☐
No ☐

If yes, please indicate how the re-entry period is determined:

Free text

Annexes:

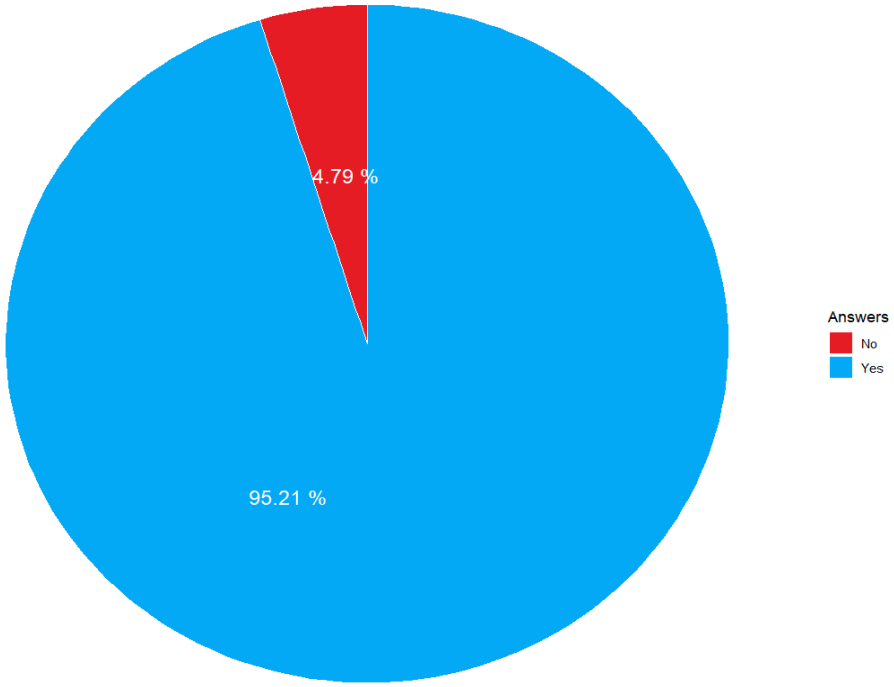
Annex A – Specialized sellers' Survey – Results (Italy - UNIMI)

Annex B – Consumer panel' Survey – Results (The Netherlands – RIVM)

Annex C – Authorities' Survey – Results (Greece - BPI)

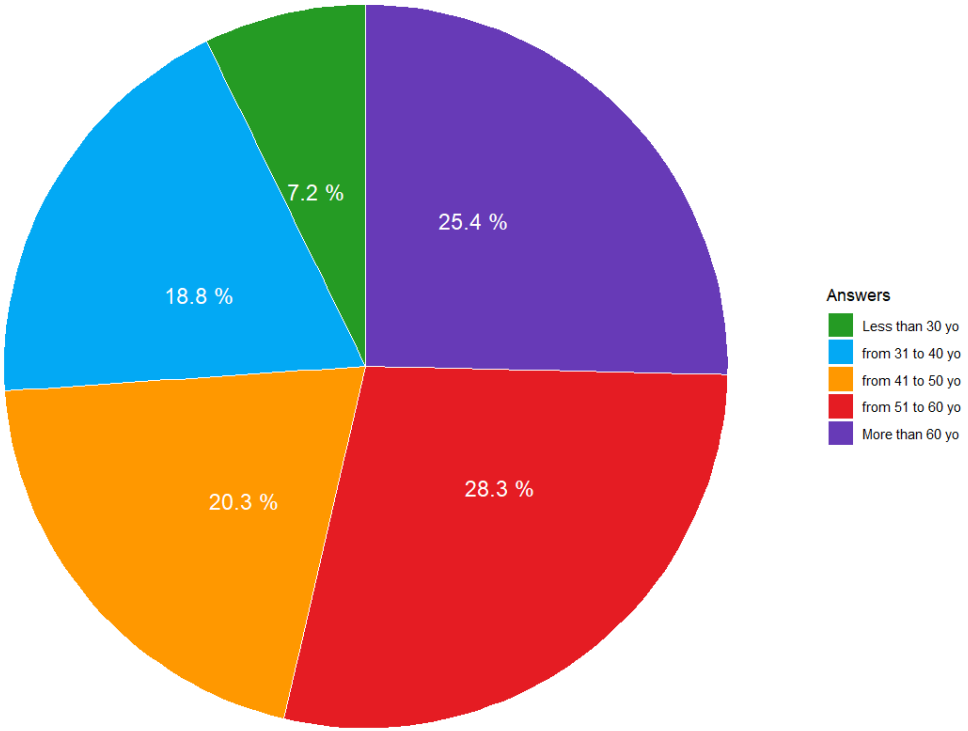
Annex A – Specialized sellers' Survey – Results as graphical output (Italy - UNIMI)

Q1 - Do you use plant protection products?
answered: 146



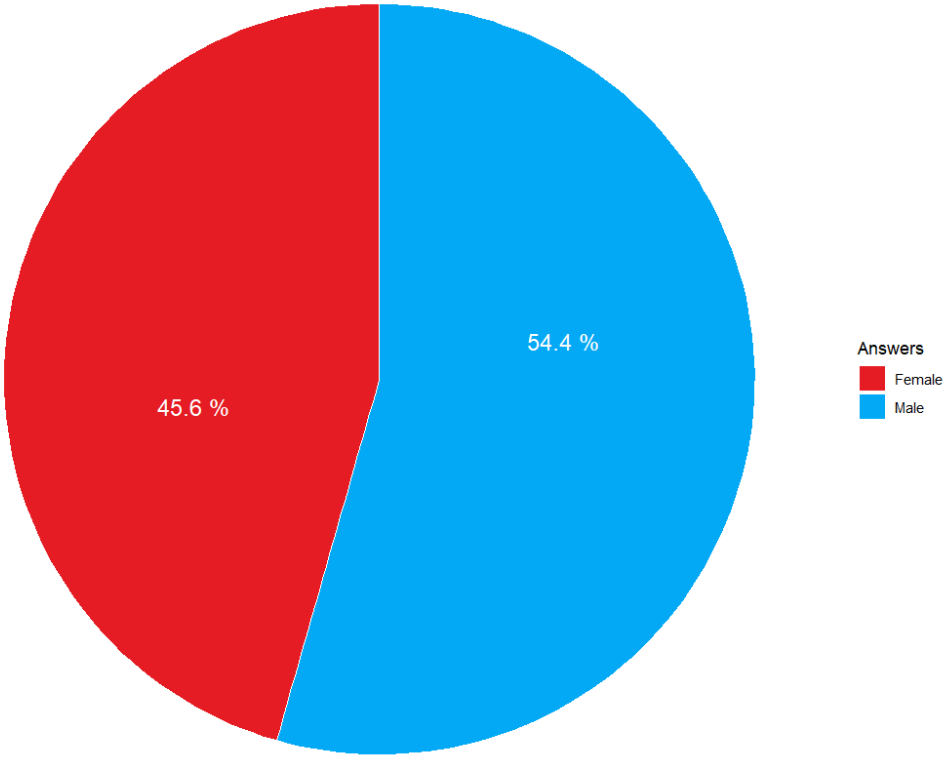
Data and methodologies non-professional PPPs exposure assessment

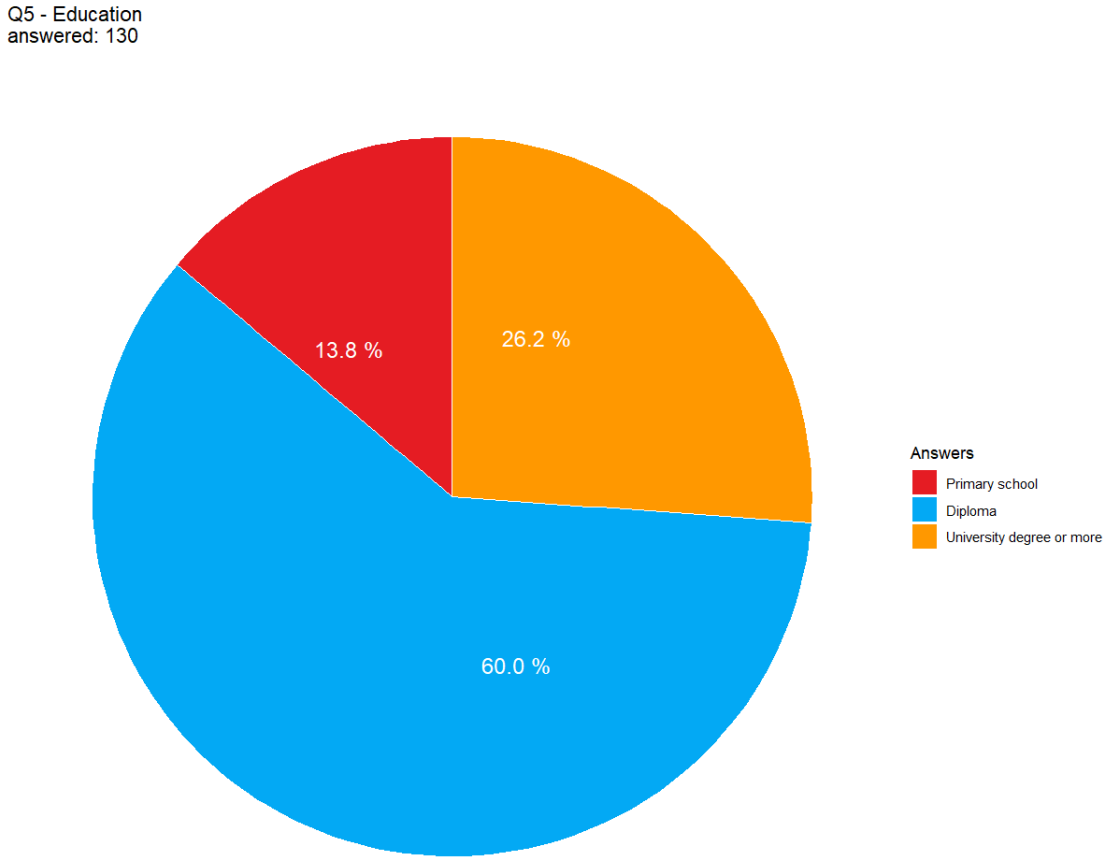
Q2 - Age
answered: 138

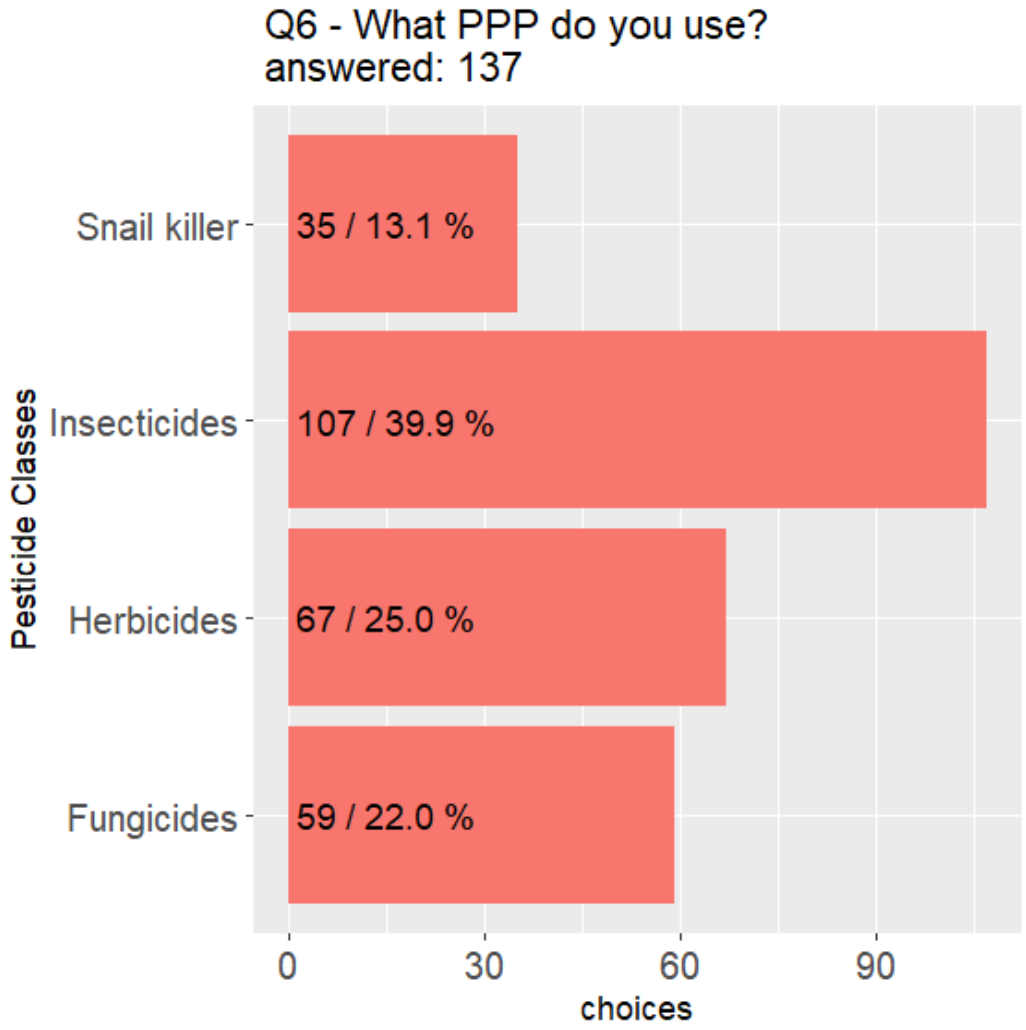


Data and methodologies non-professional PPPs exposure assessment

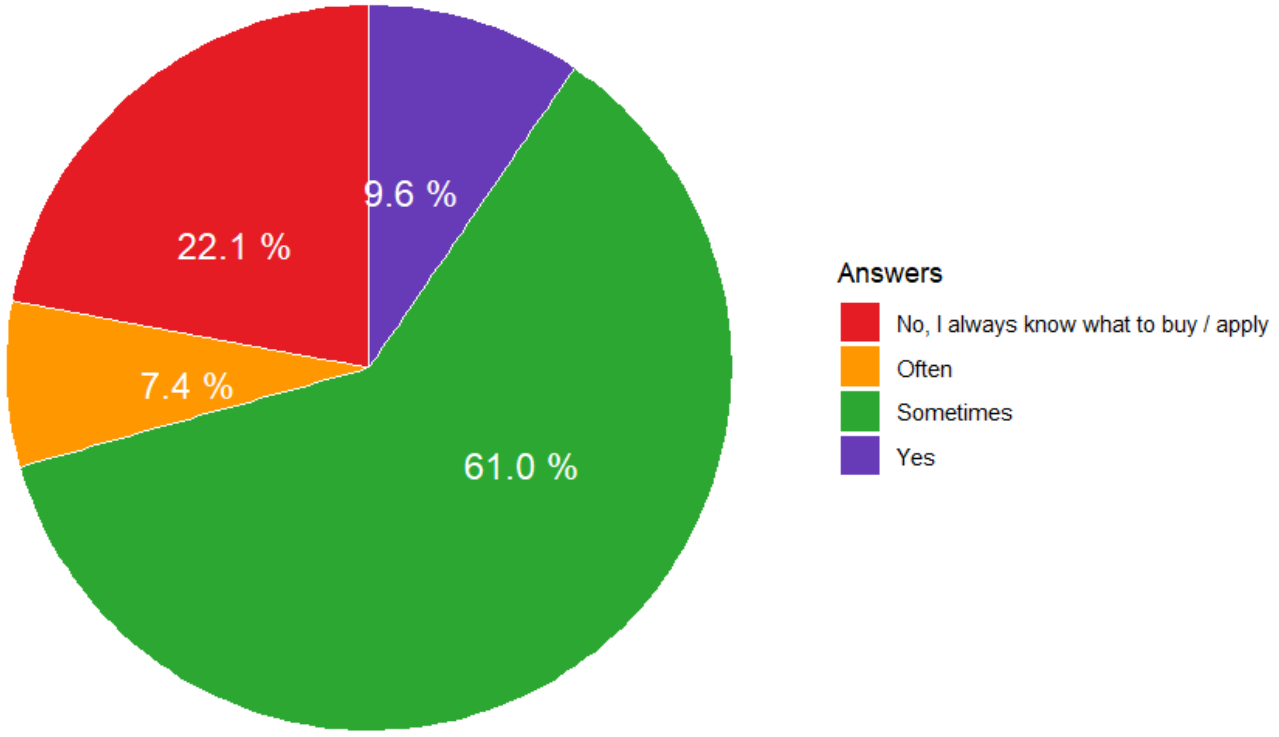
Q3 - Gender
answered: 136

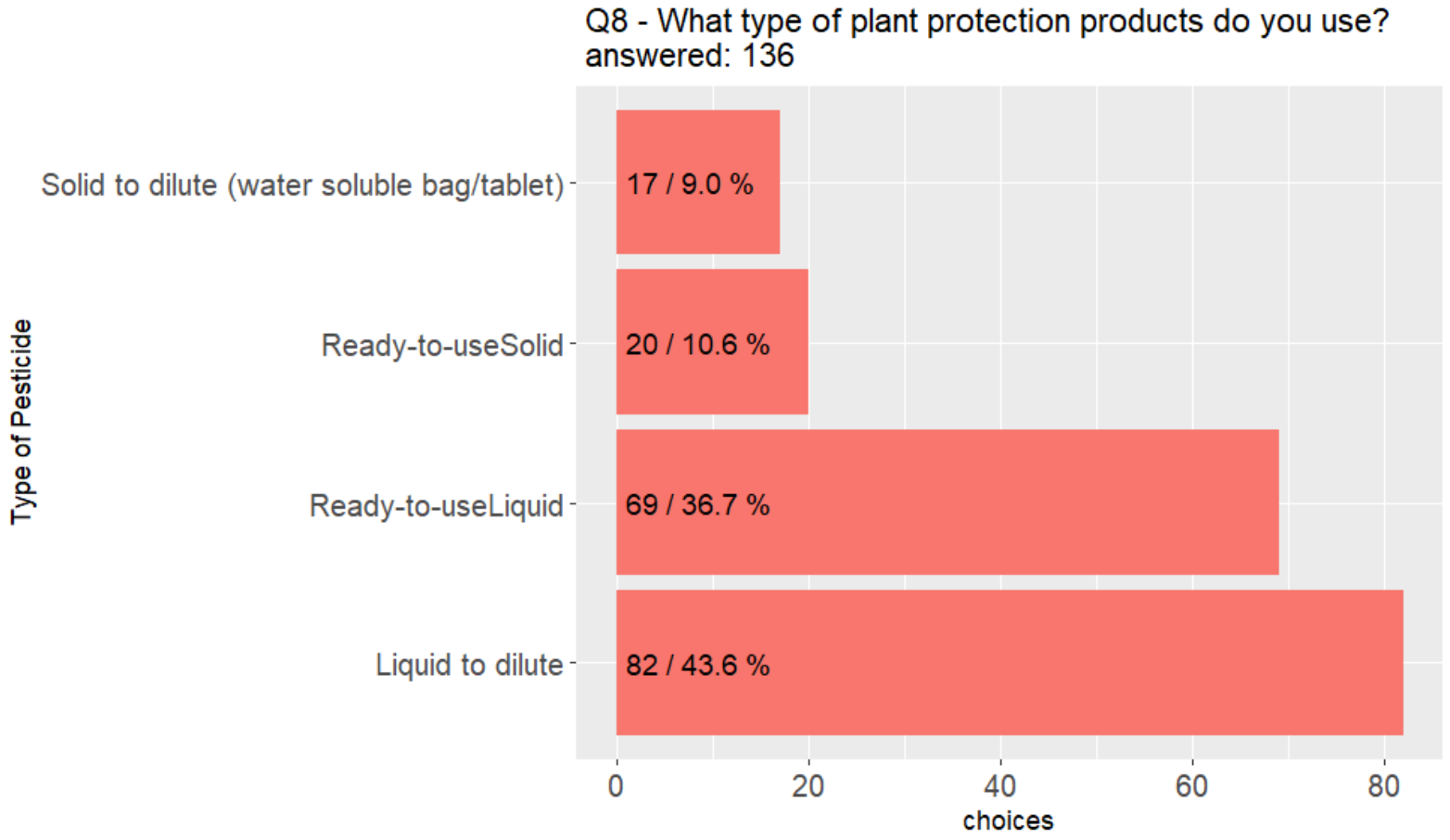


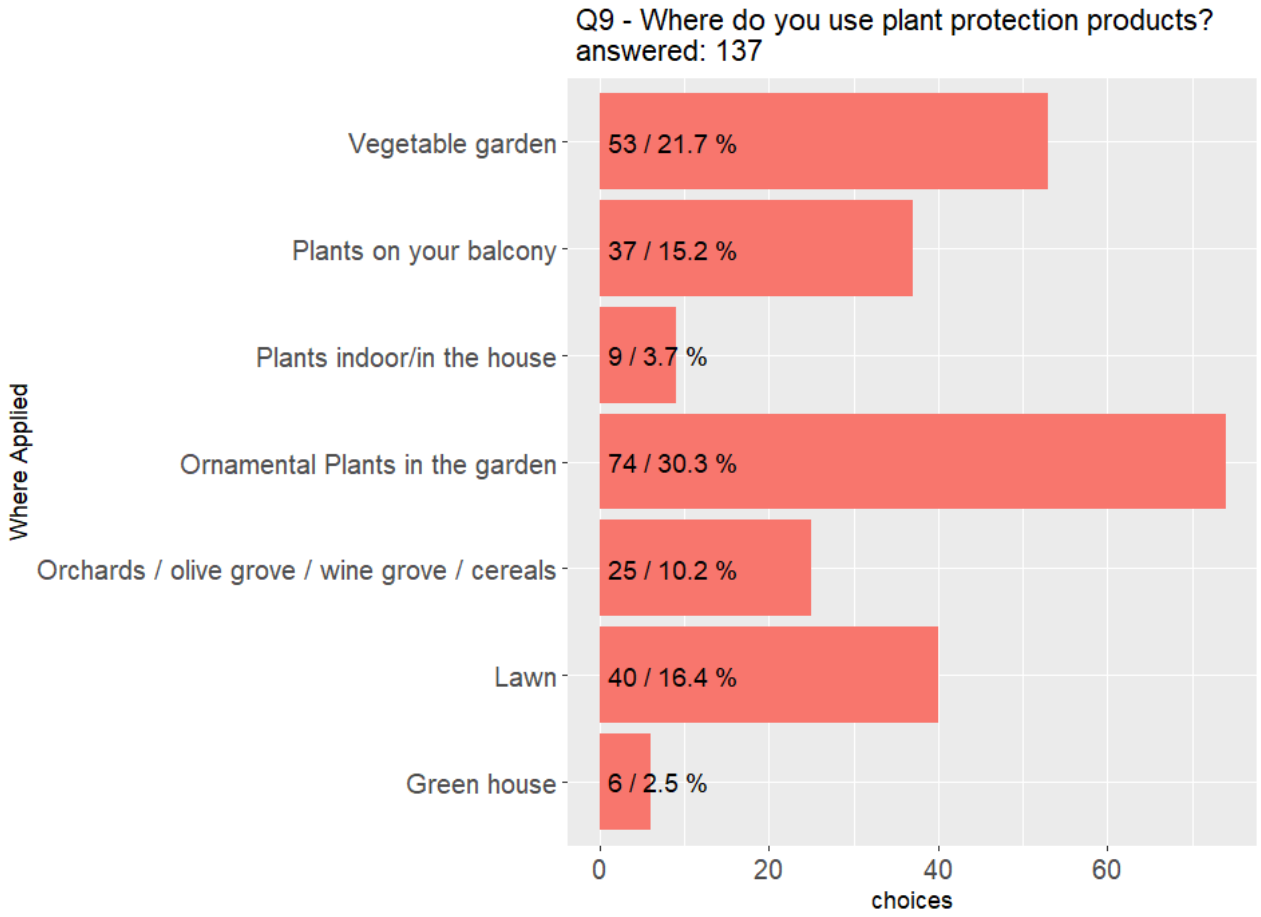




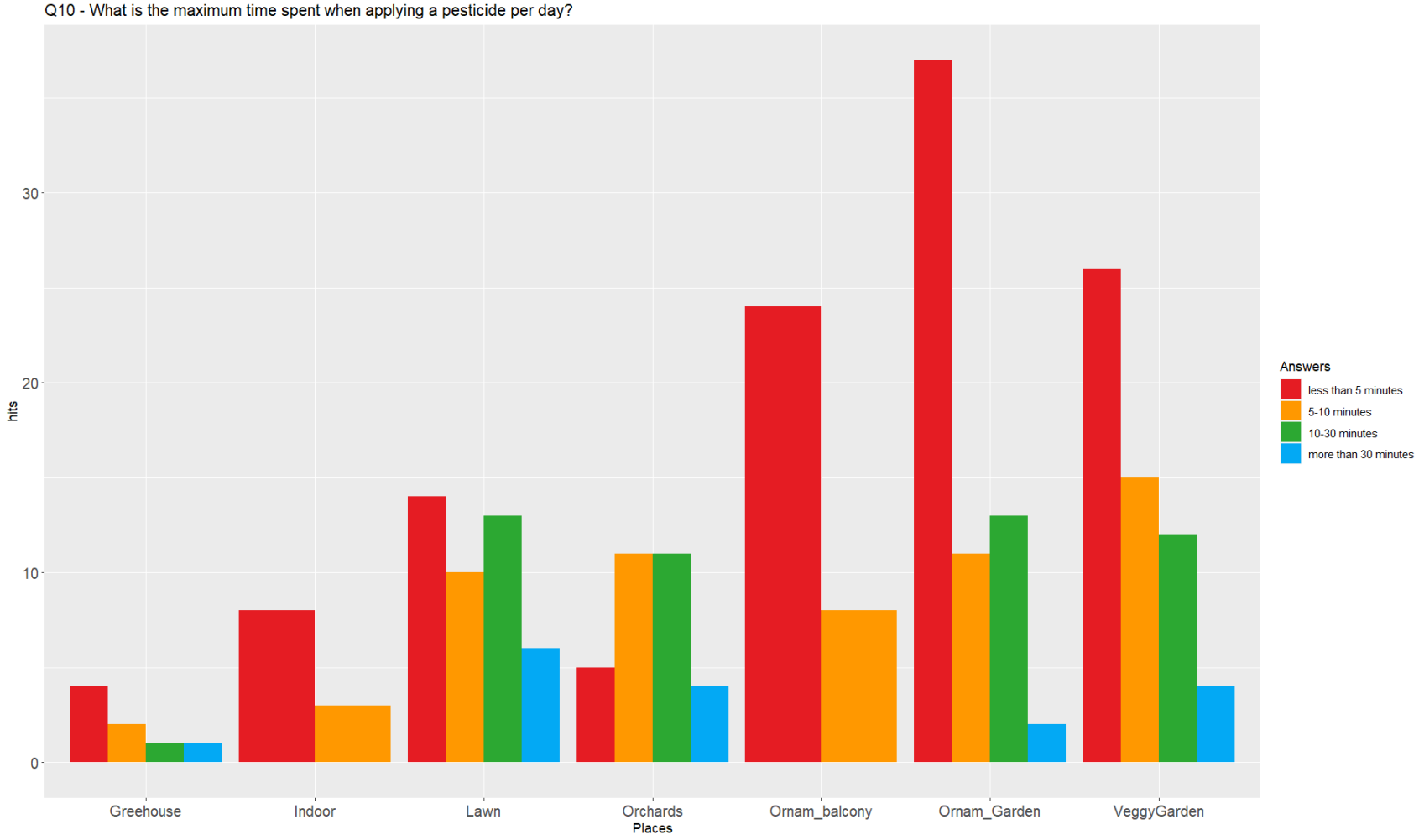
Q7 - When you buy a plant protection product, do you ask the seller for advice?
answered: 136







Data and methodologies non-professional PPPs exposure assessment



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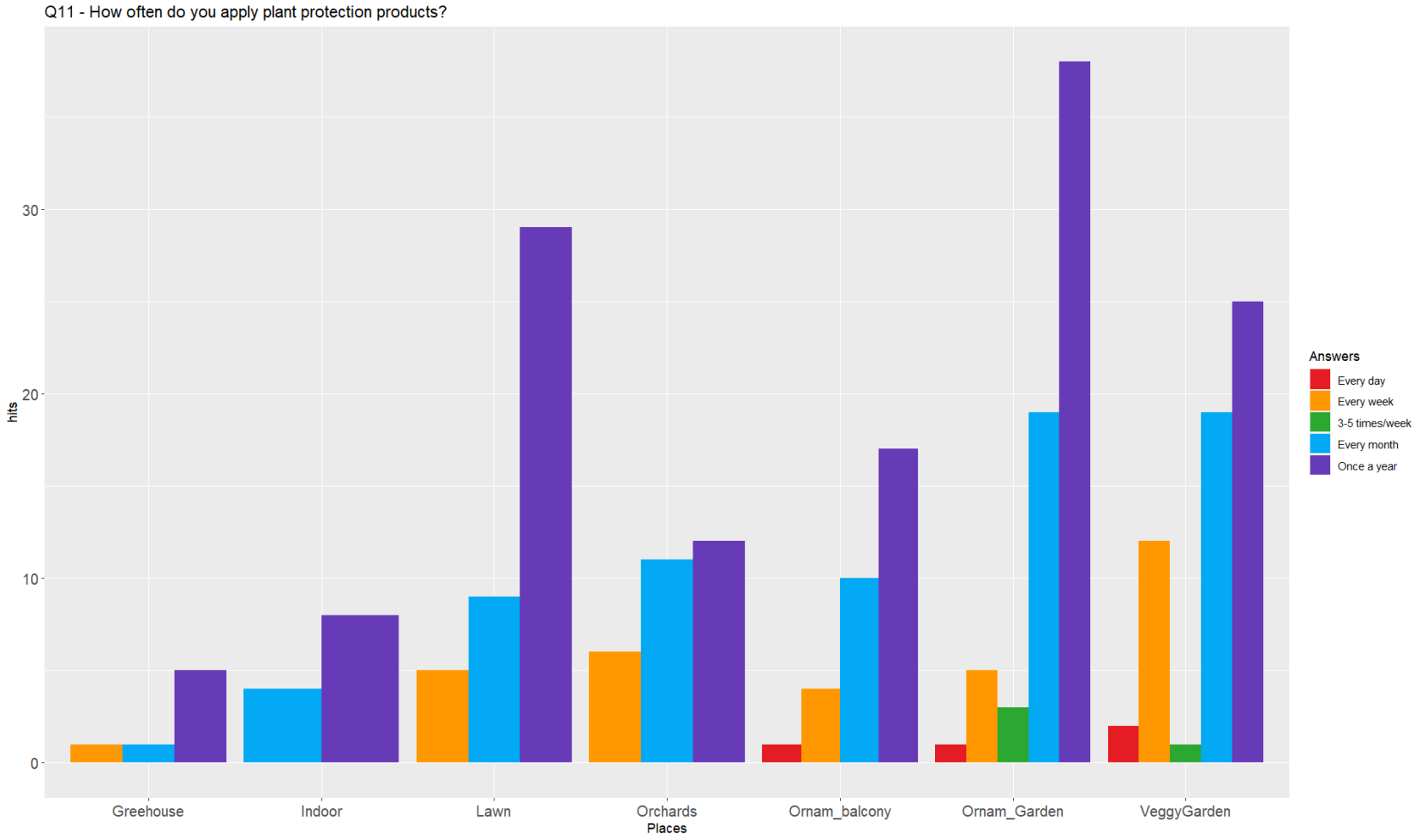

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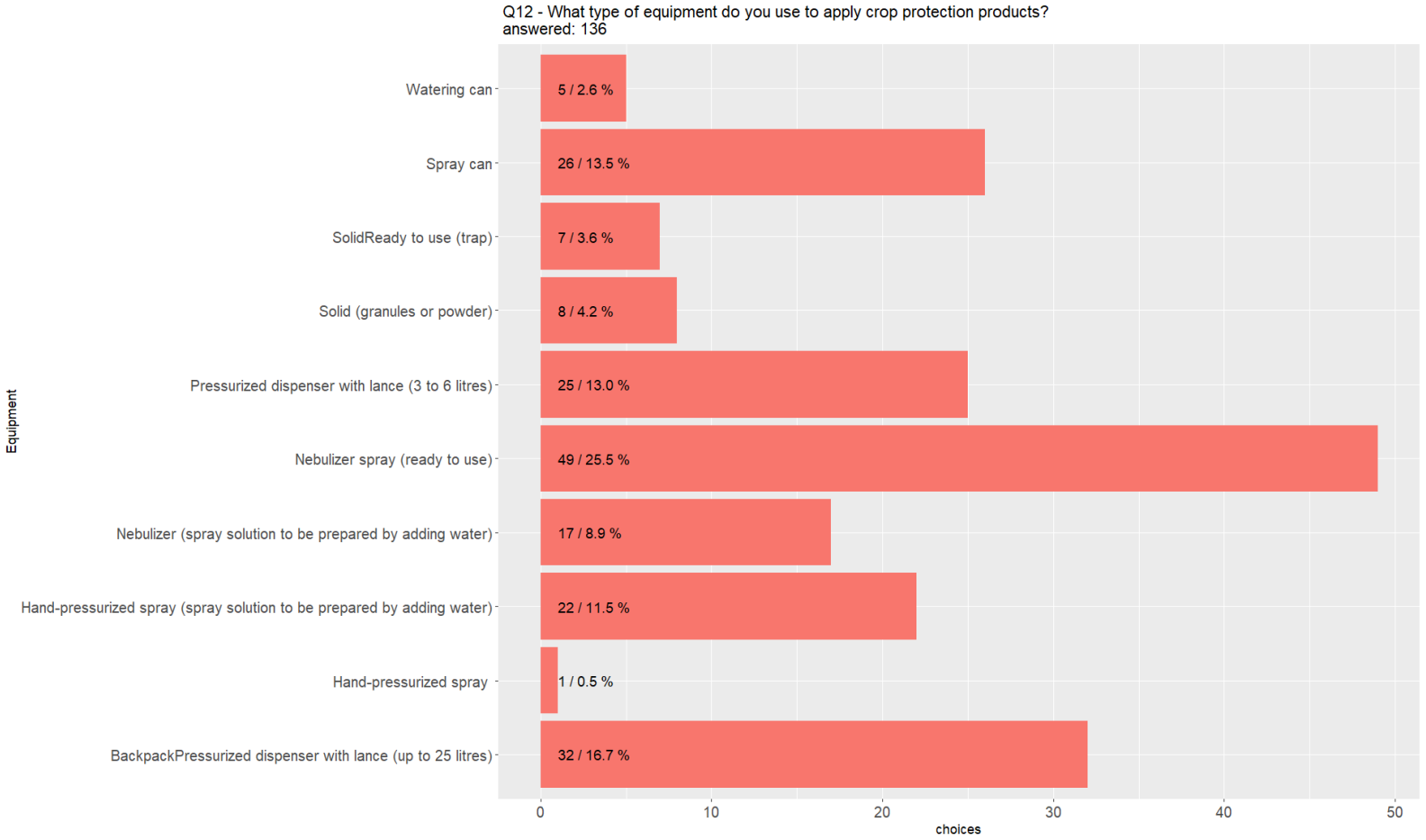
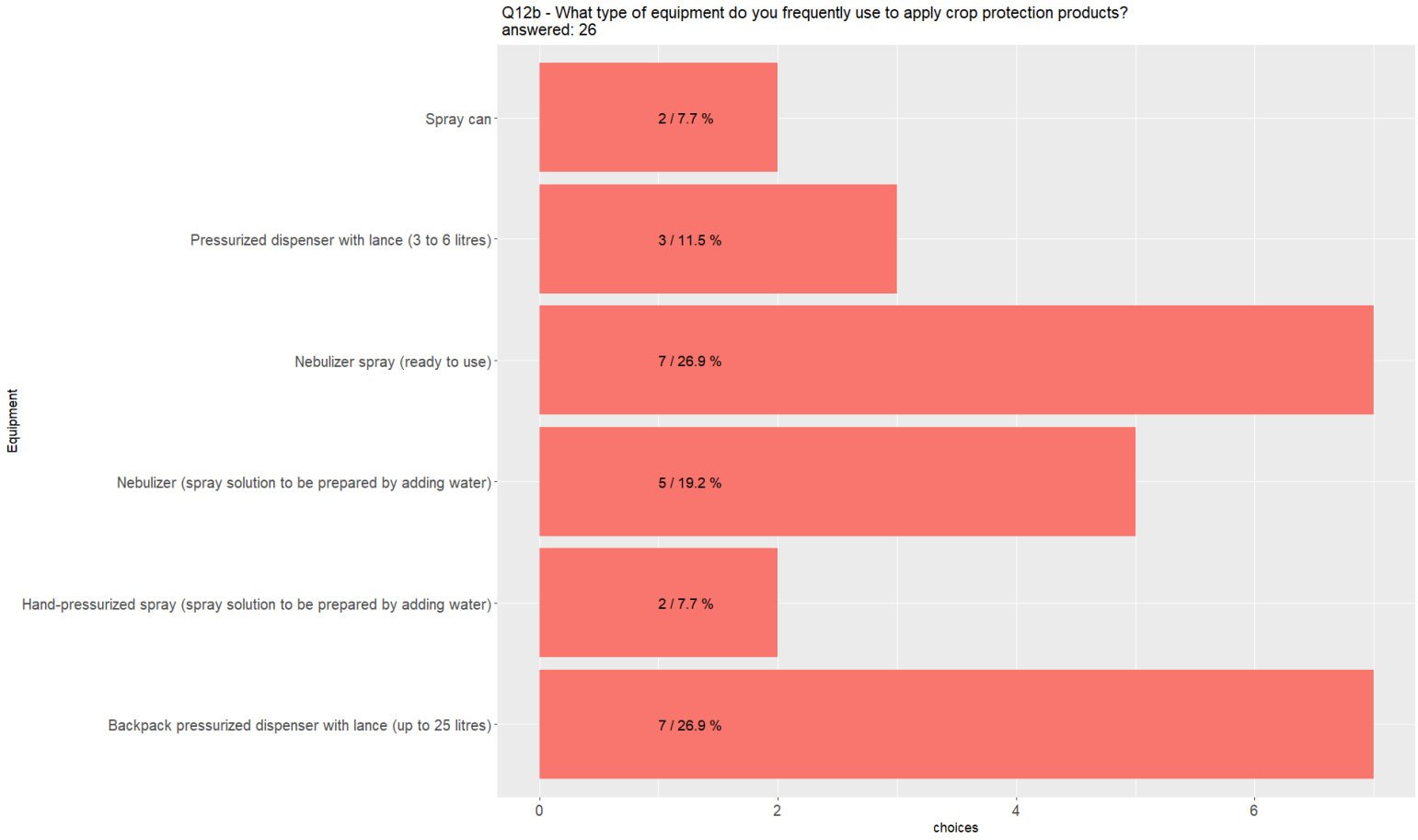


Data and methodologies non-professional PPPs exposure assessment



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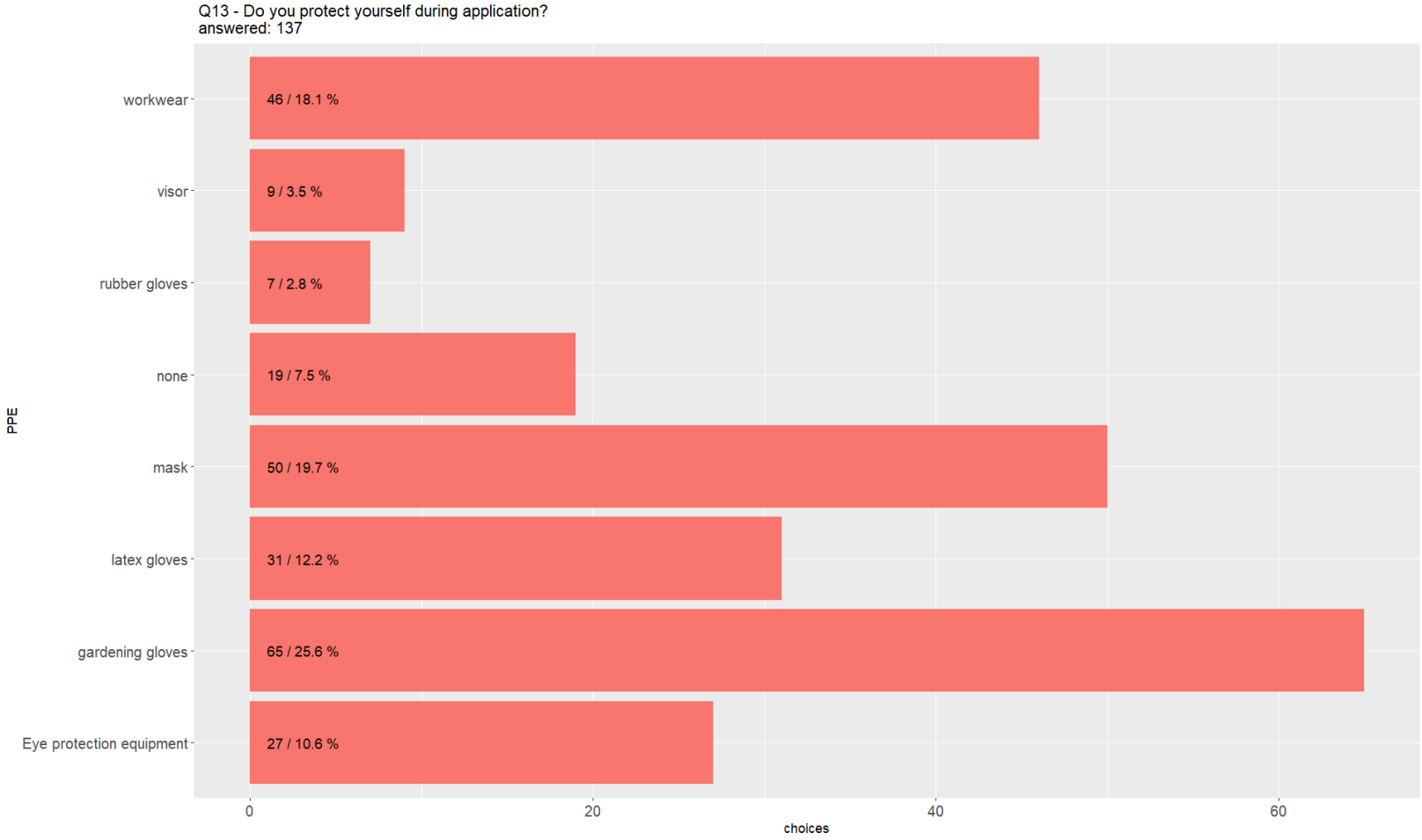
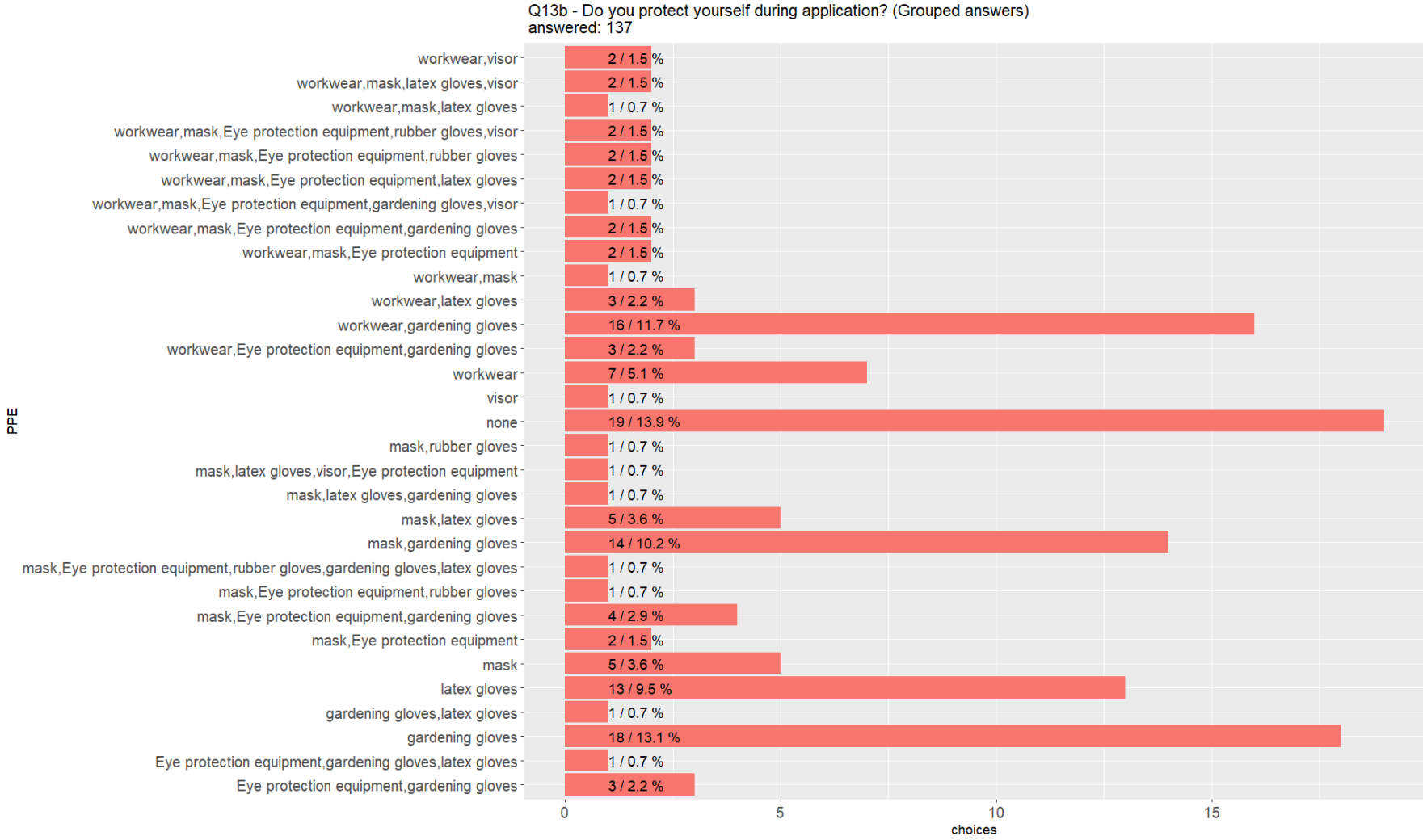
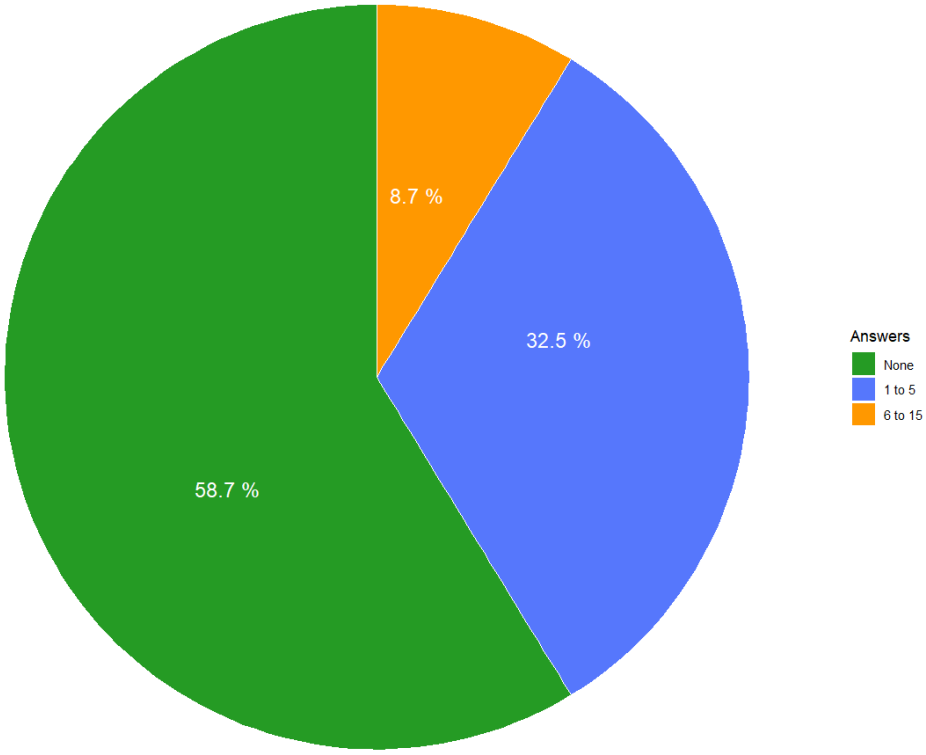


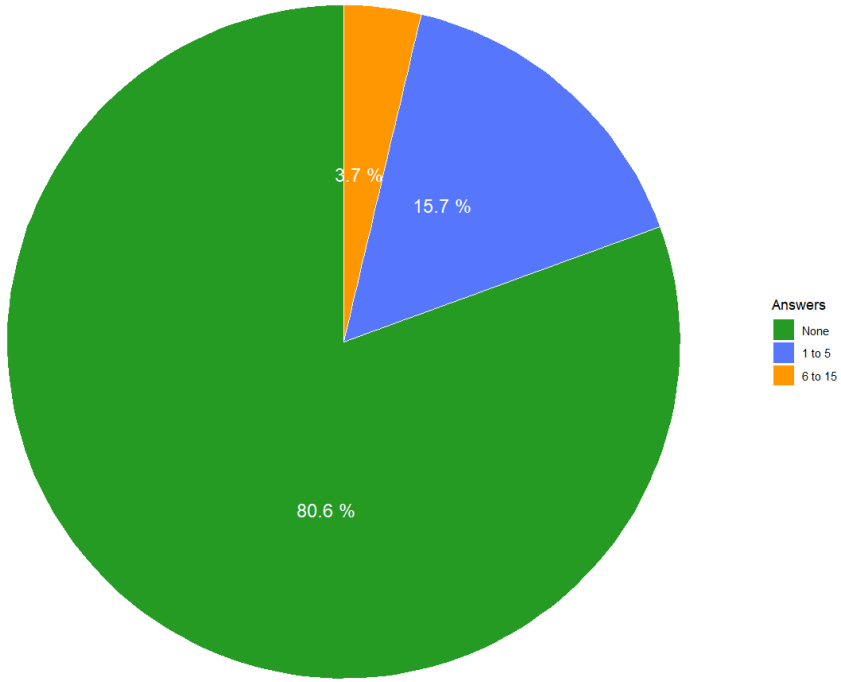
Data and methodologies non-professional PPPs exposure assessment



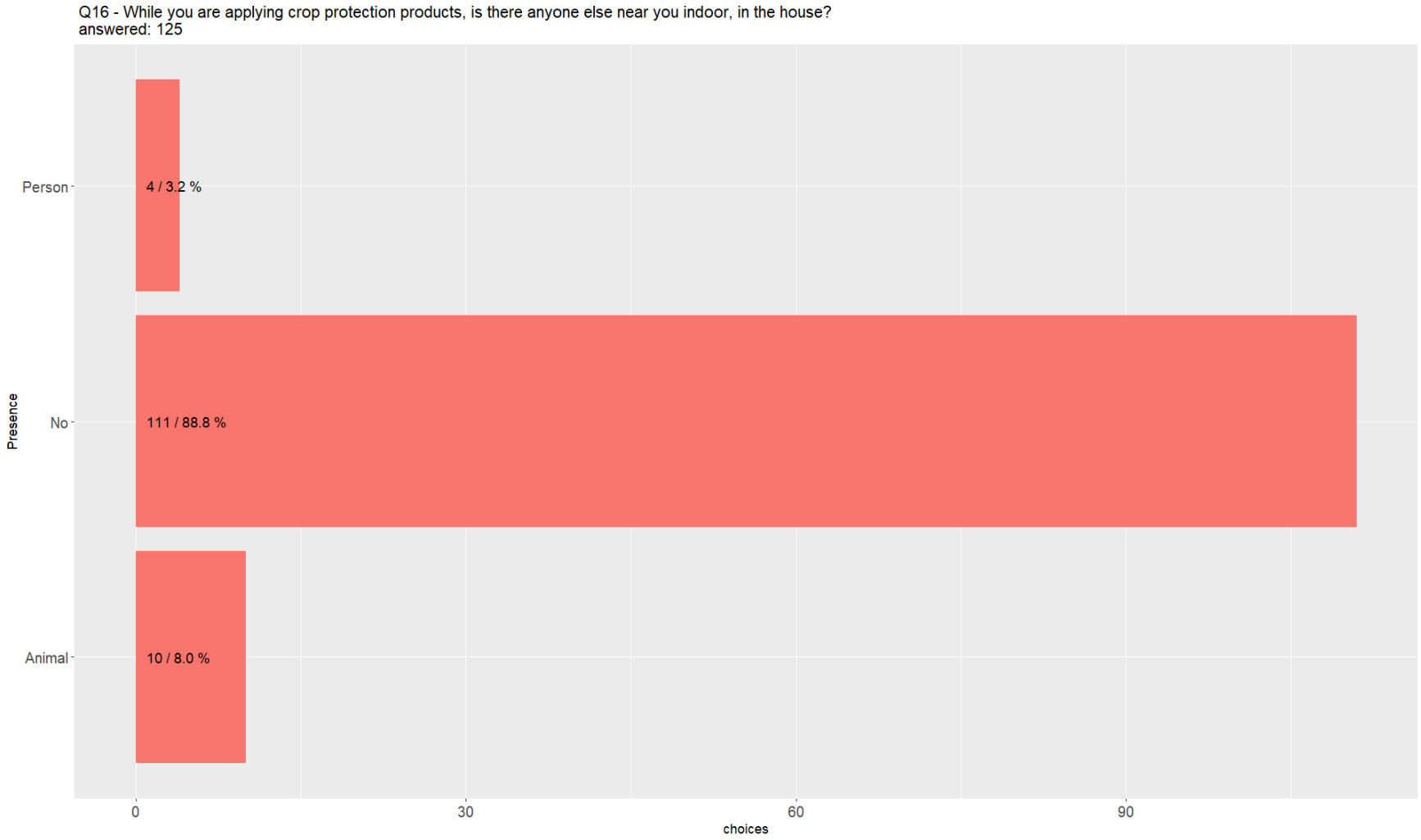
Q14 - Please, indicate the number of SMALL / MEDIUM potted plants treated with plant protection products indoor, in your house
answered: 126

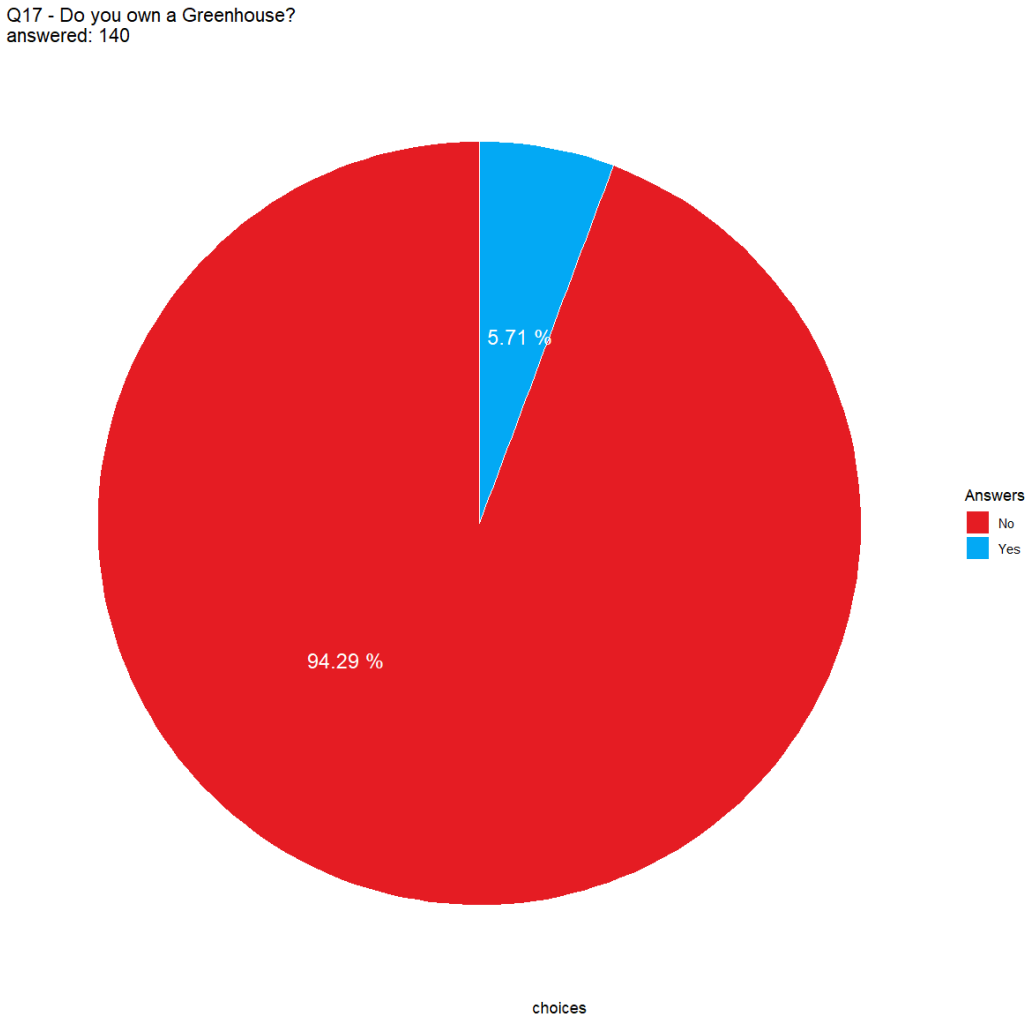


Q15 - Please, indicate the number of HIGH potted plants treated with plant protection products indoor, in your house.
answered: 108



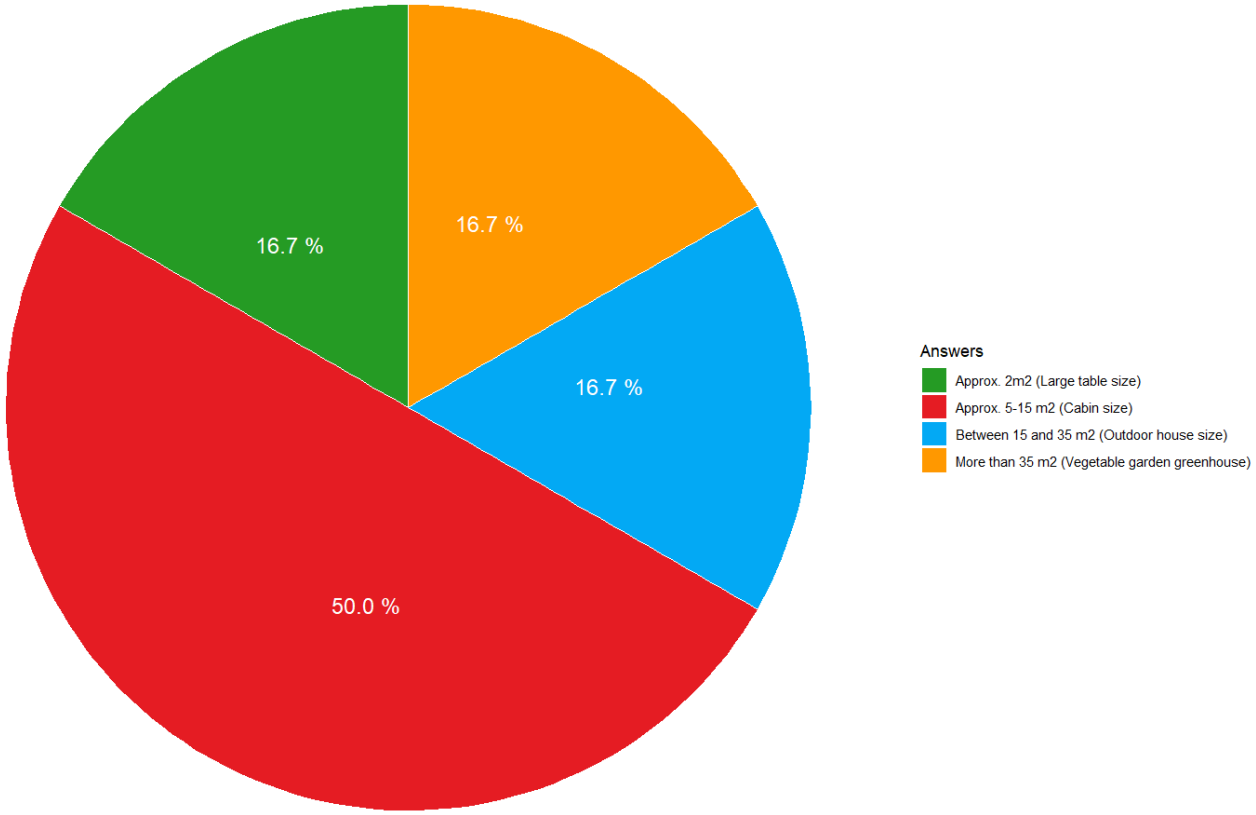
Data and methodologies non-professional PPPs exposure assessment



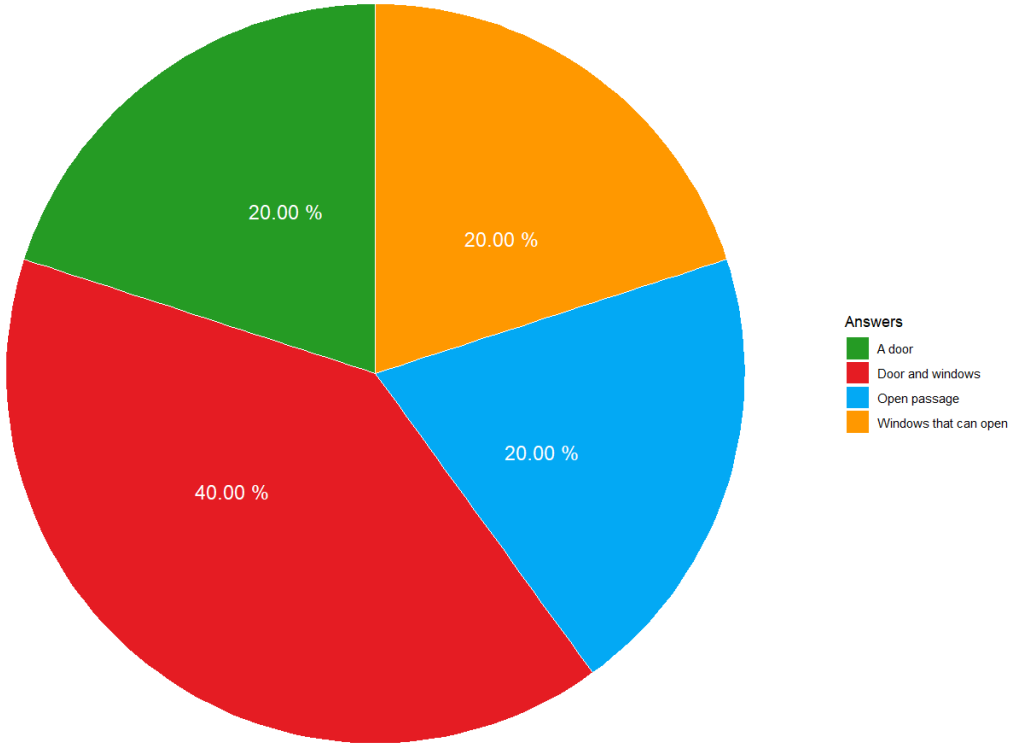


Data and methodologies non-professional PPPs exposure assessment

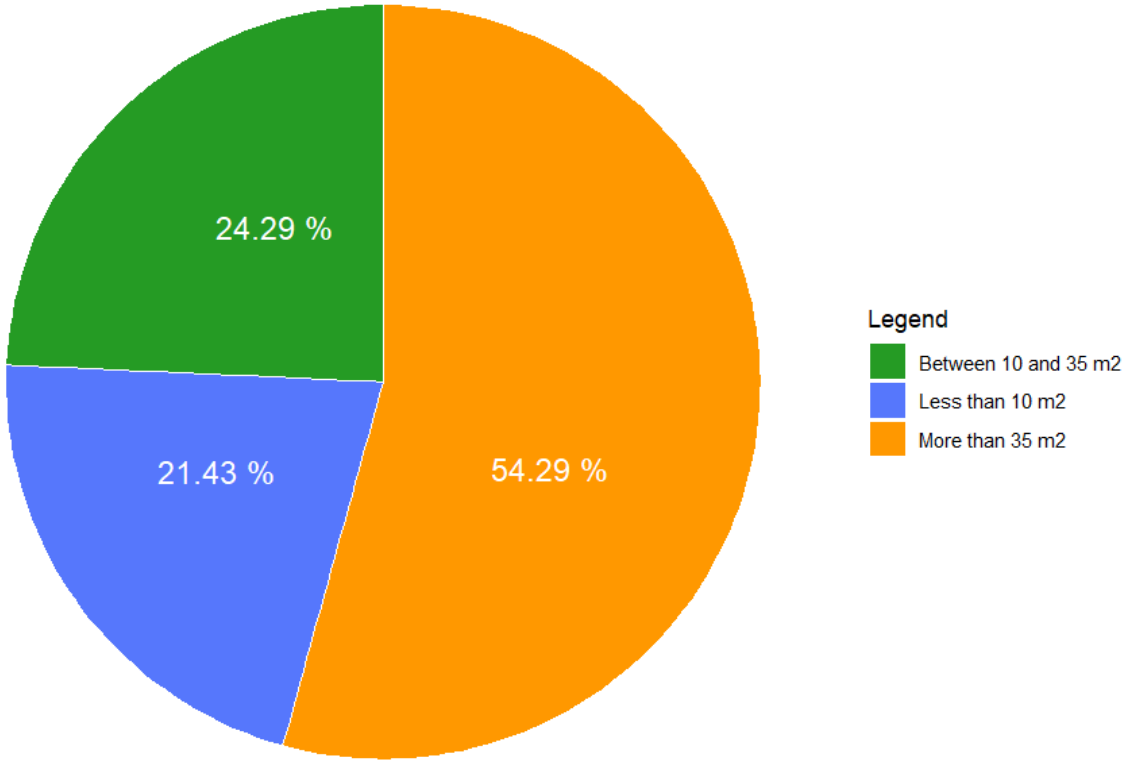
Q18 - If yes, what is the size of the greenhouse?
answered: 6



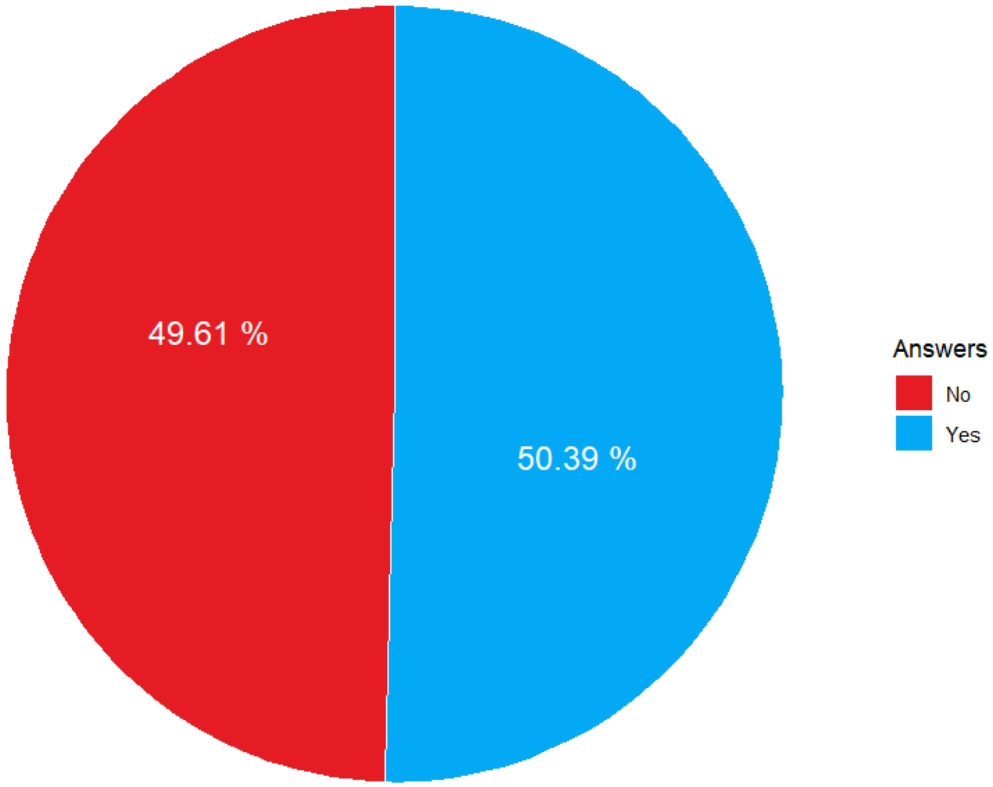
Q19 - What type of opening does it have?
answered: 5



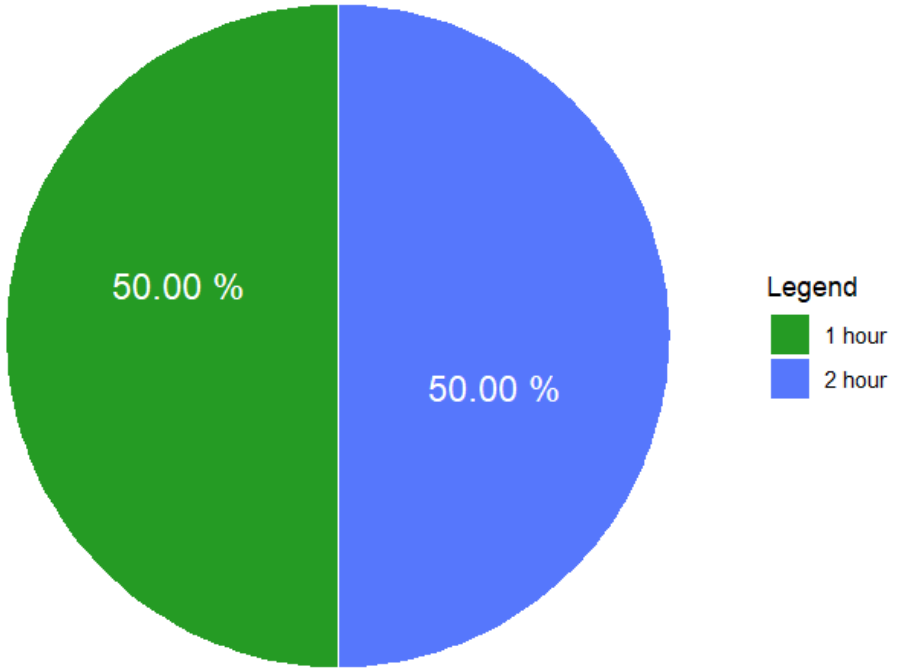
Q20 - In case you have a (vegetable) garden, what is the approximate size in square meters not including terrace or pavement?
answered: 70



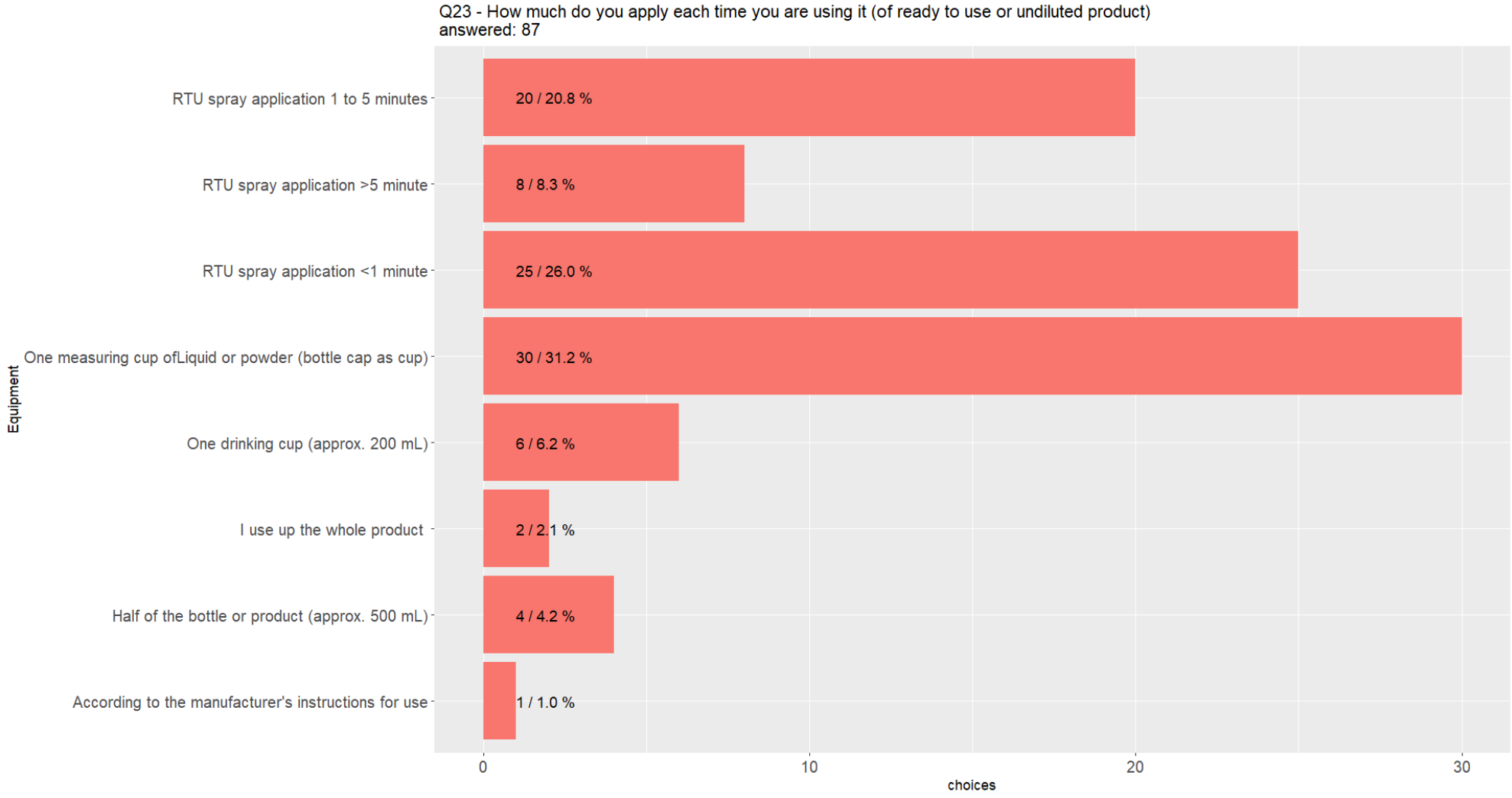
Q21 - Do you re-enter the lawn or gardening (re-potting, inspection, irrigation, harvesting) within 24 hours after treatment?
answered: 129



Q22 - If the maximum time taken for the daily application of a pesticide is more than 30 minutes, please indicate the approximate time for the selected location
answered: 4



Data and methodologies non-professional PPPs exposure assessment

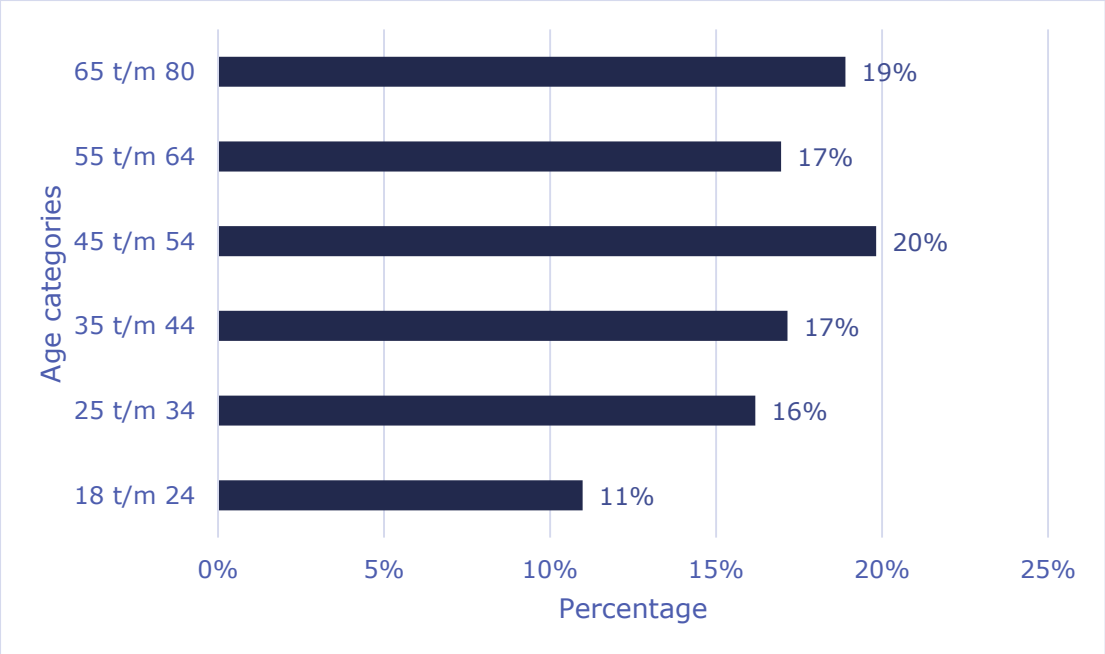


Annex B – Consumer panel' Survey – Results (The Netherlands – RIVM)

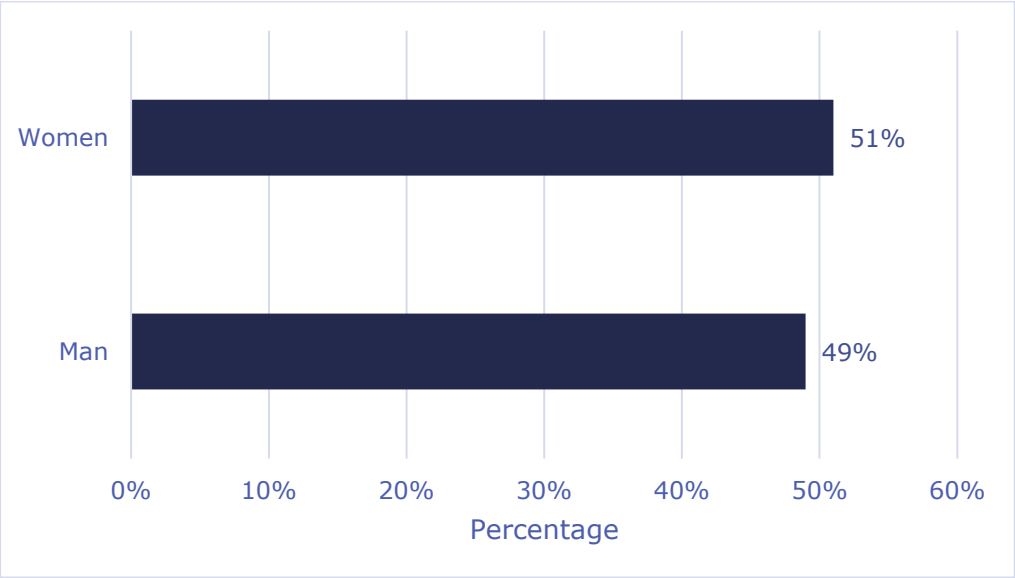
Results related to the responders (age and gender) and general information about their household and garden.

7.1 Personal and residential data on the selection questions:

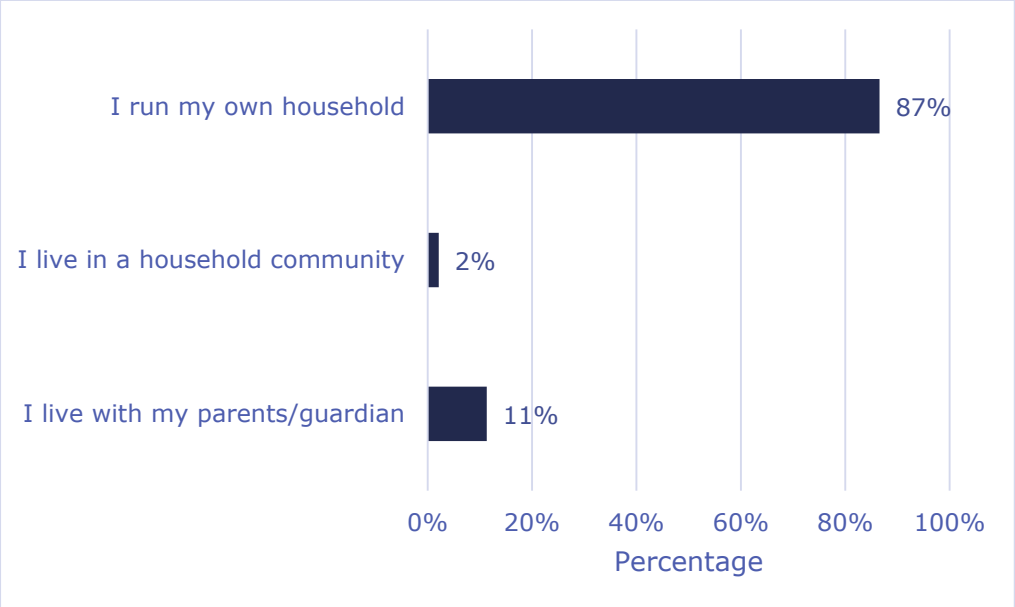
B1 – Age
Answered: 583



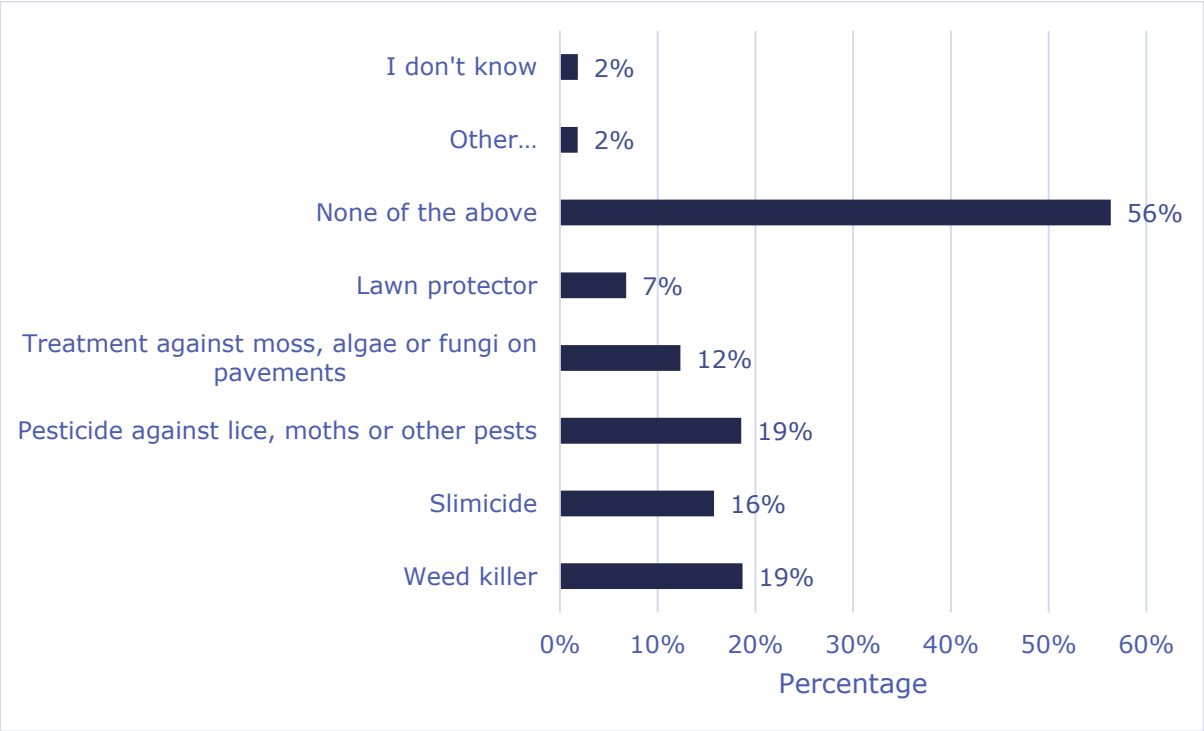
B2 – Gender
Answered: 583



B3 – What is your current living situation?
Answered: 583

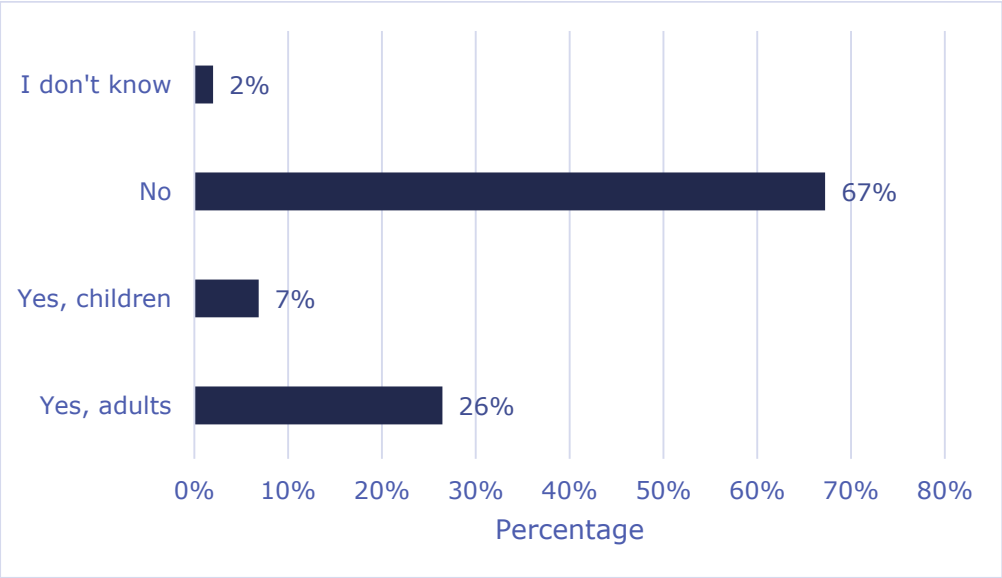


B4 – Do you use one or more of the following plant protection products?
Answered: 505

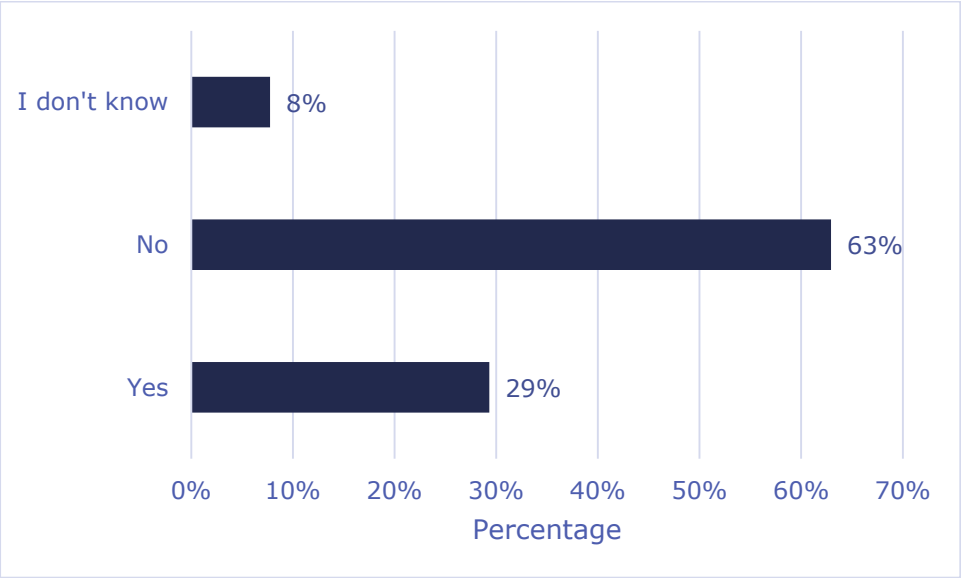


7.2 Residential data of responders who use plant protection products:

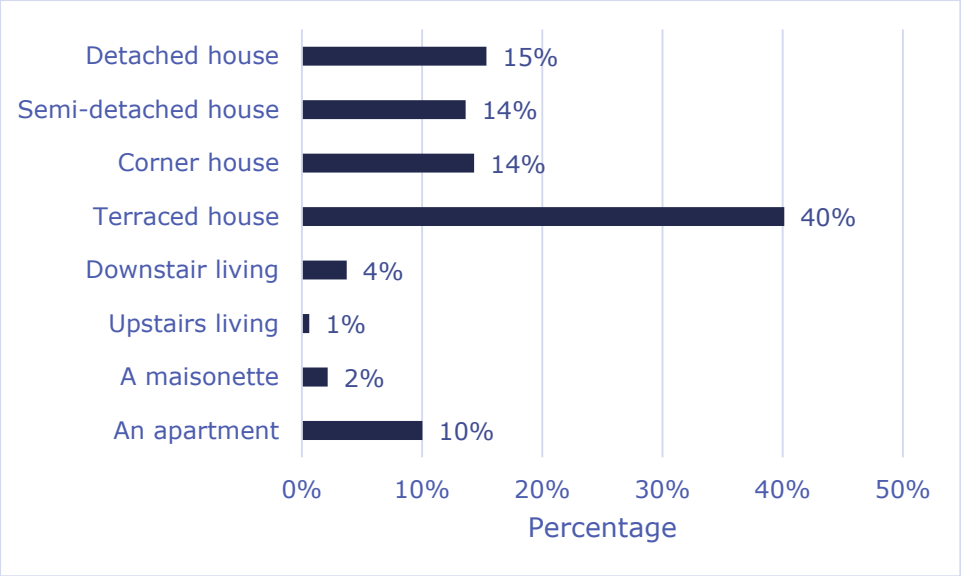
B5 – Are other people present during application of those products?
Answered: 211



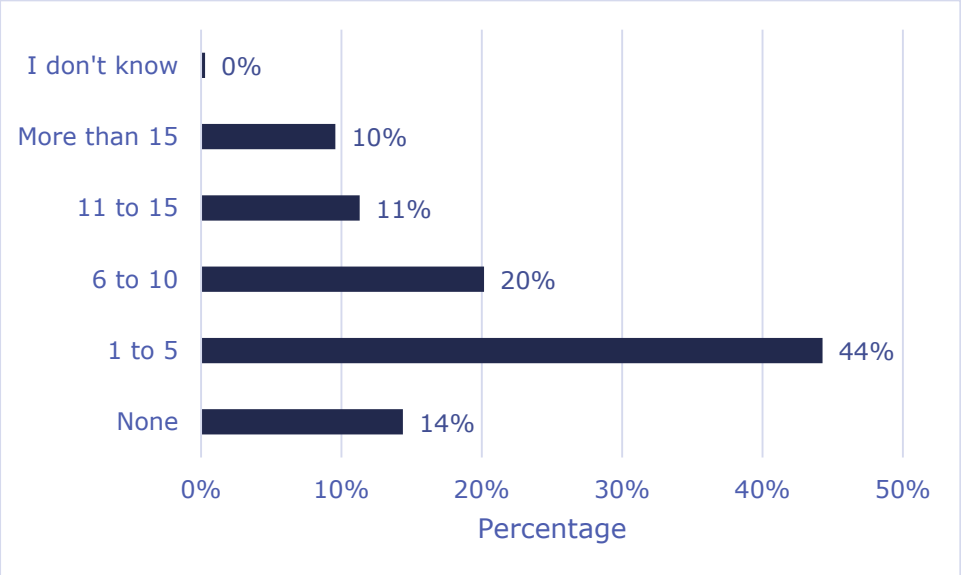
B6 – Do you or others re-enter the area where you applied the product within 24 hours after use?
Answered: 211



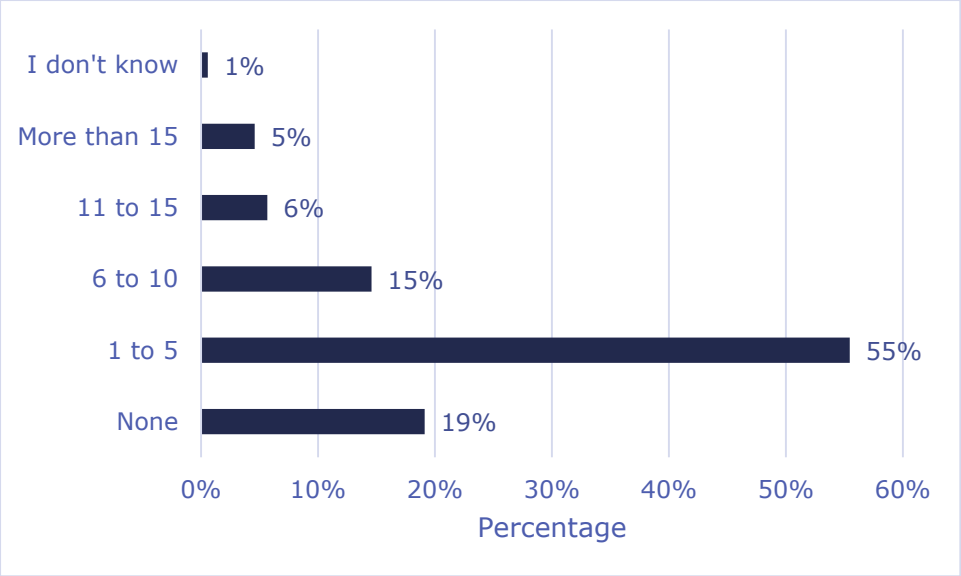
B7 – In what type of housing do you live?
Answered: 211



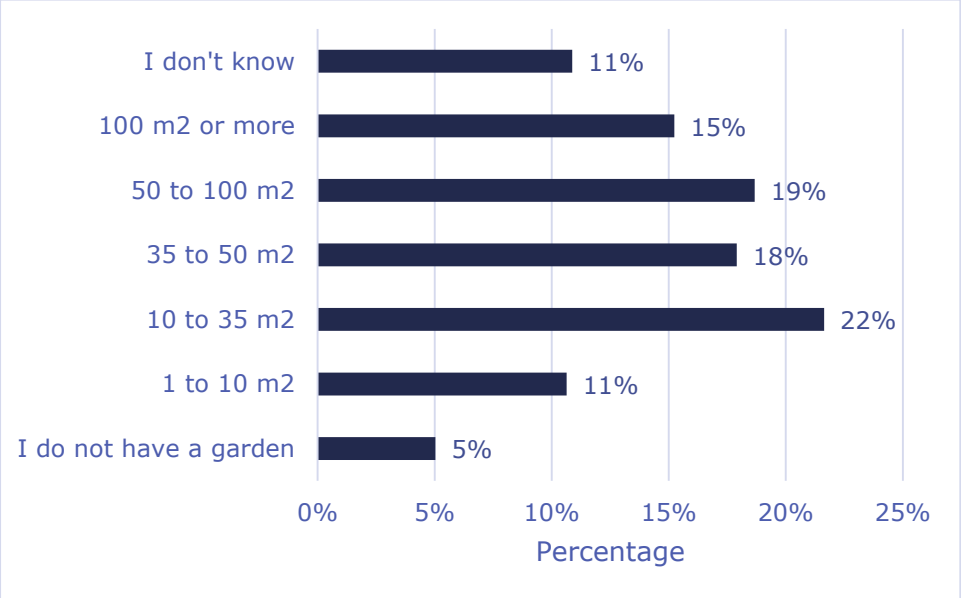
B8 – How many small/medium sized plants do you have within the house and/or balkony?
Answered: 211



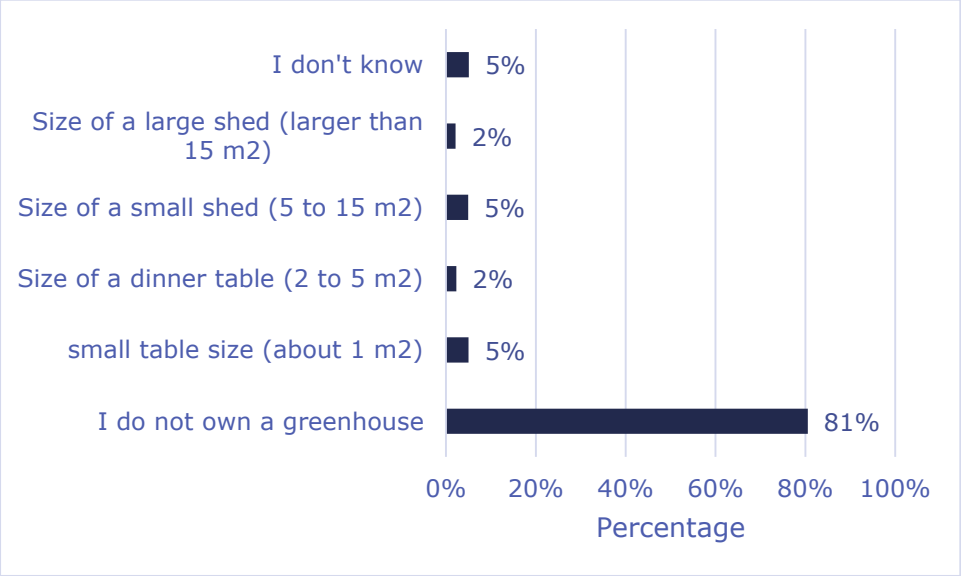
B9 – How many large sized plants do you have within the house and/or balkony?
Answered: 211



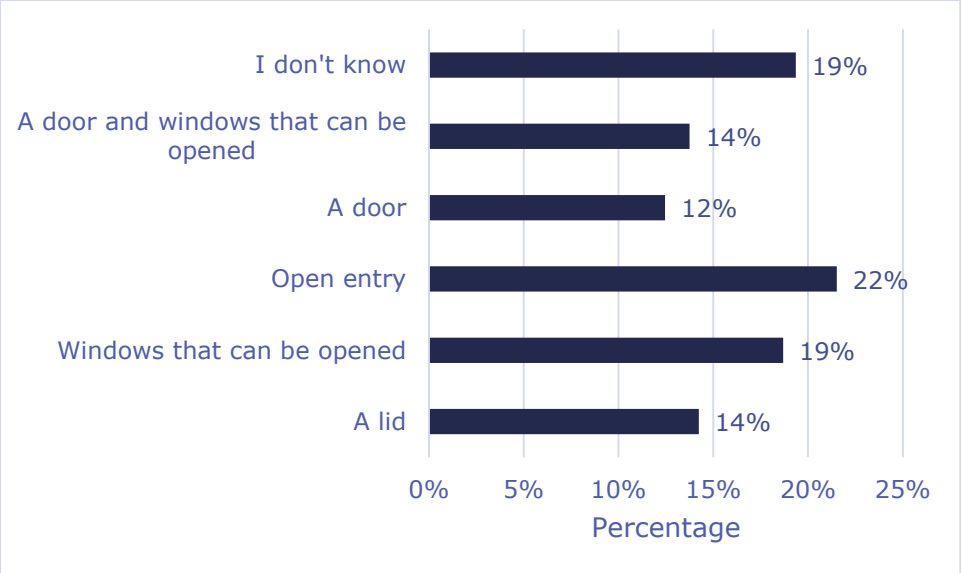
B10 – In case you have a (kitchen) garden, what is the approximate size in square meters not including terrace or pavement?
Answered: 211



B11 – In case you own a greenhouse, what is the size of the greenhouse?
Answered: 211

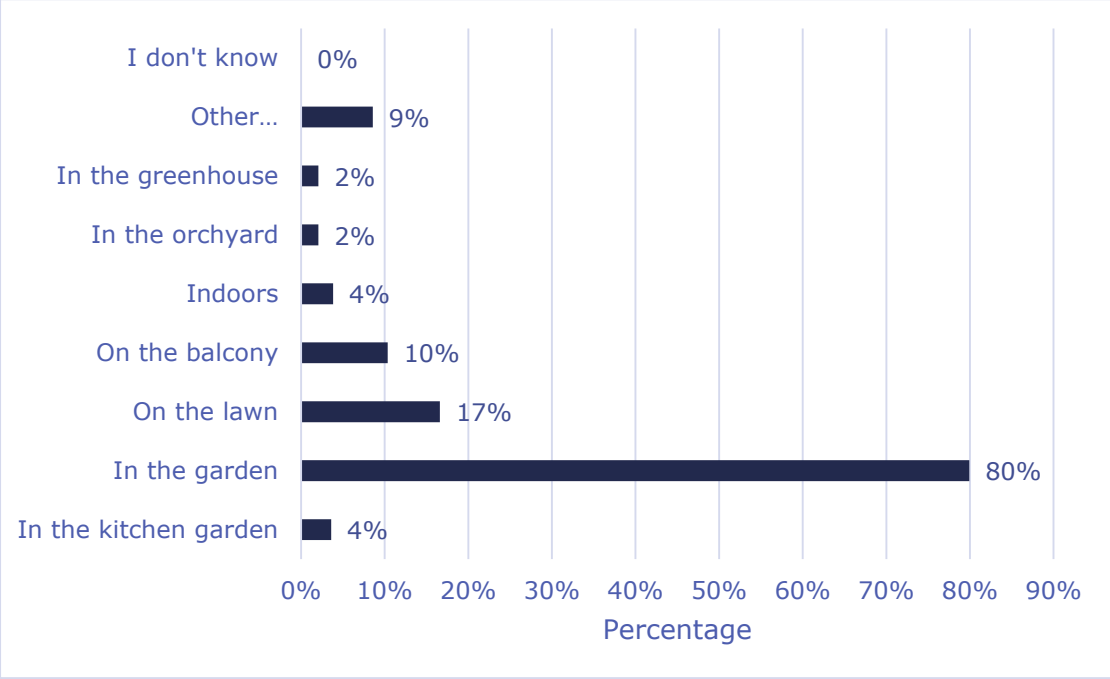


B12 – What type of openings does the greenhouse have?
Answered: 41

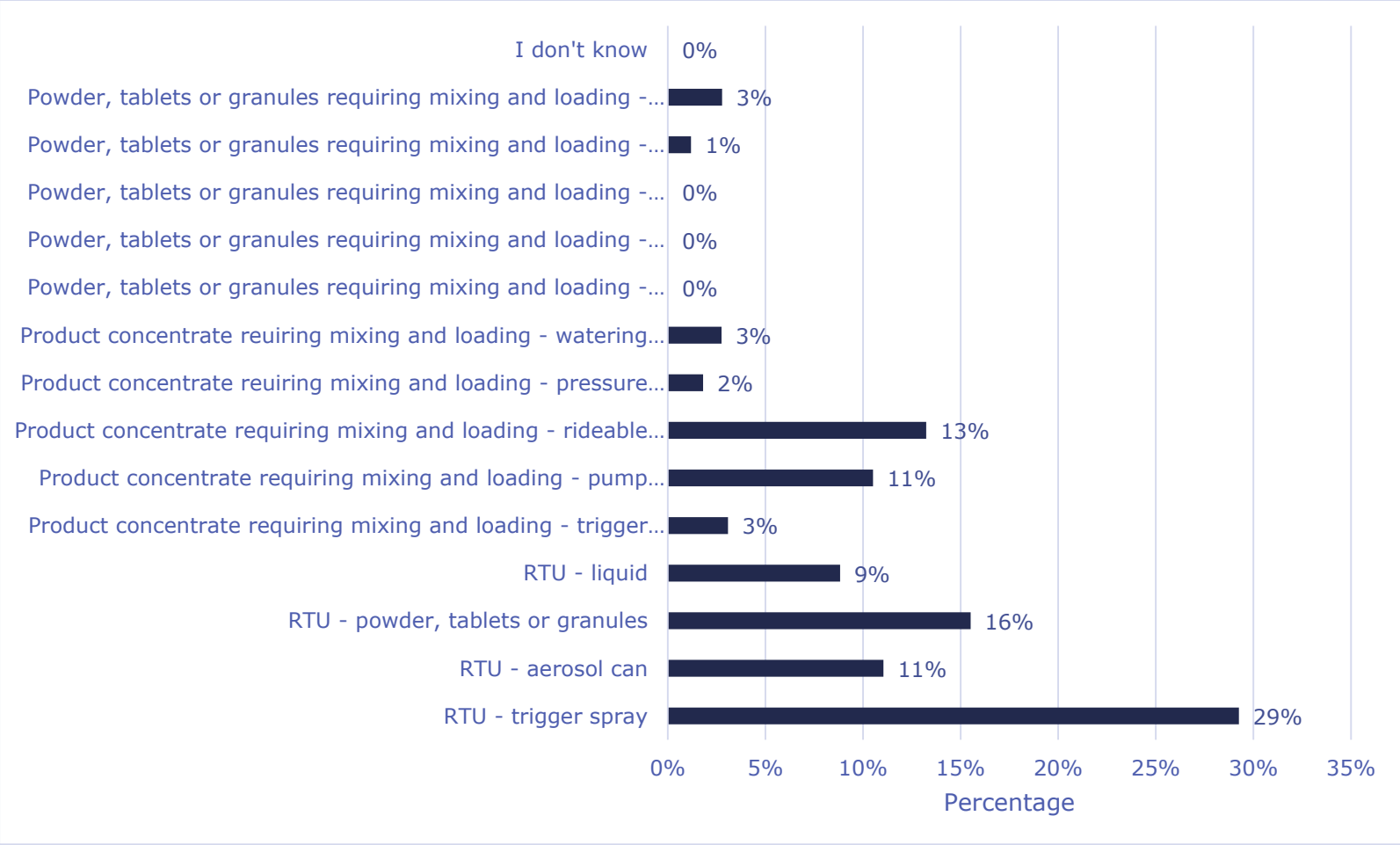


7.3 Weed killer

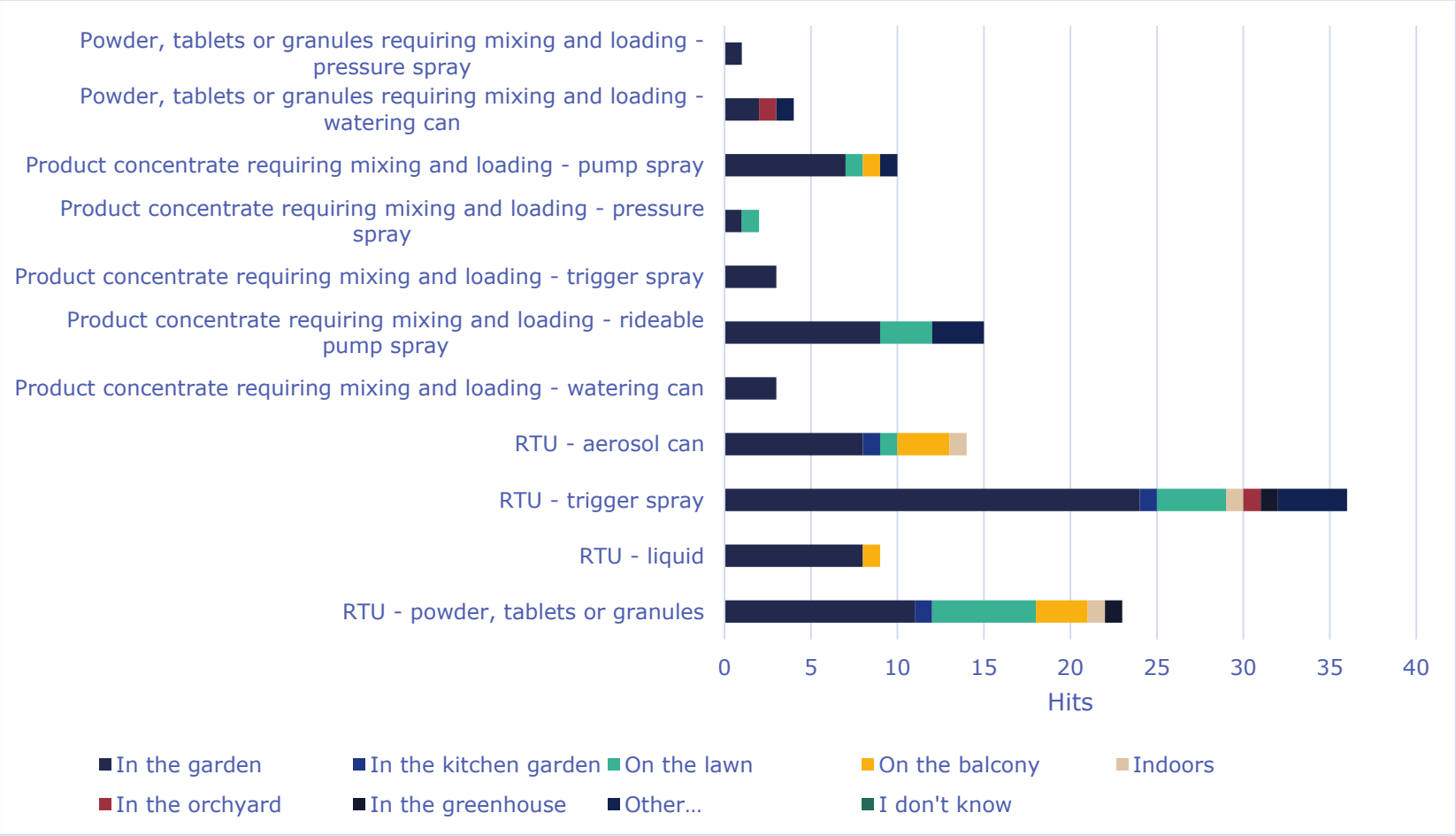
B13 – Can you specify where you apply weedkiller?
Answered: 94



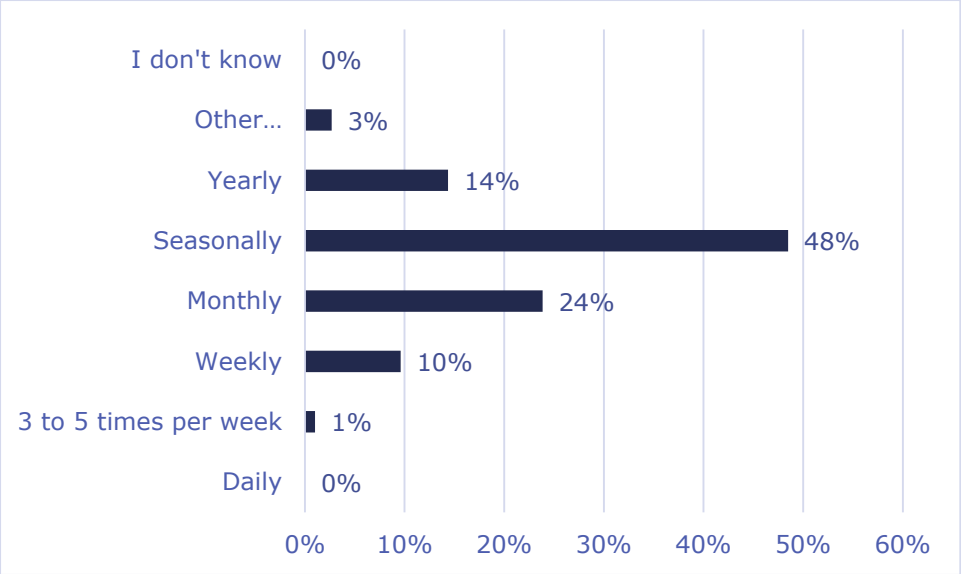
B14 – Can you specify what application type you use?
Answered: 94



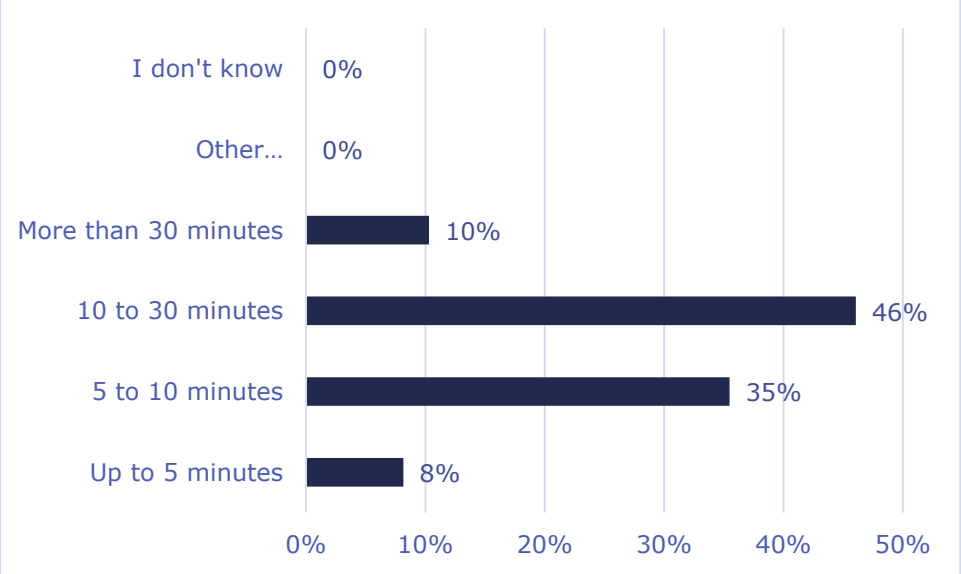
B15 – Location of use per application type



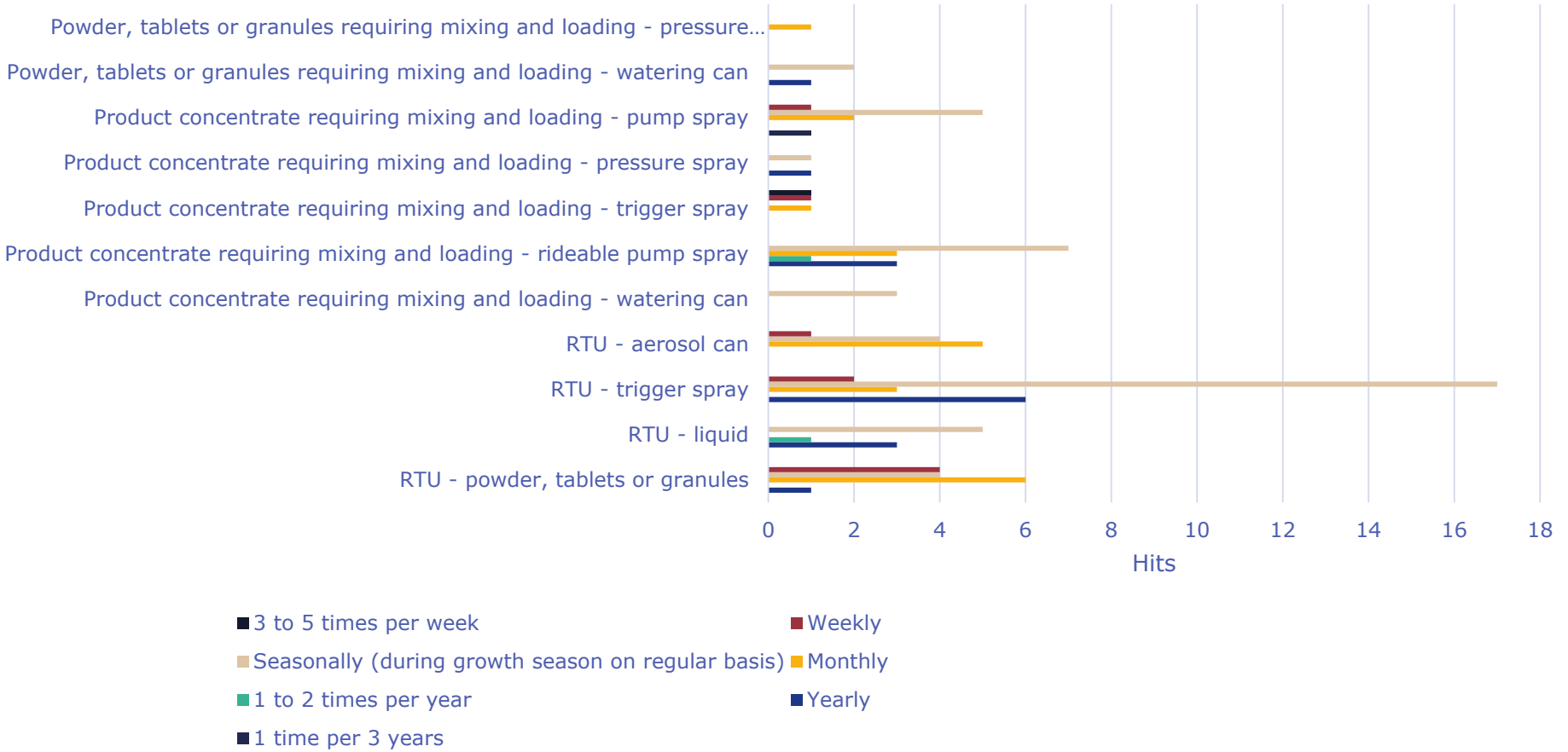
B16 – How often do you use that product?
Answered: 94



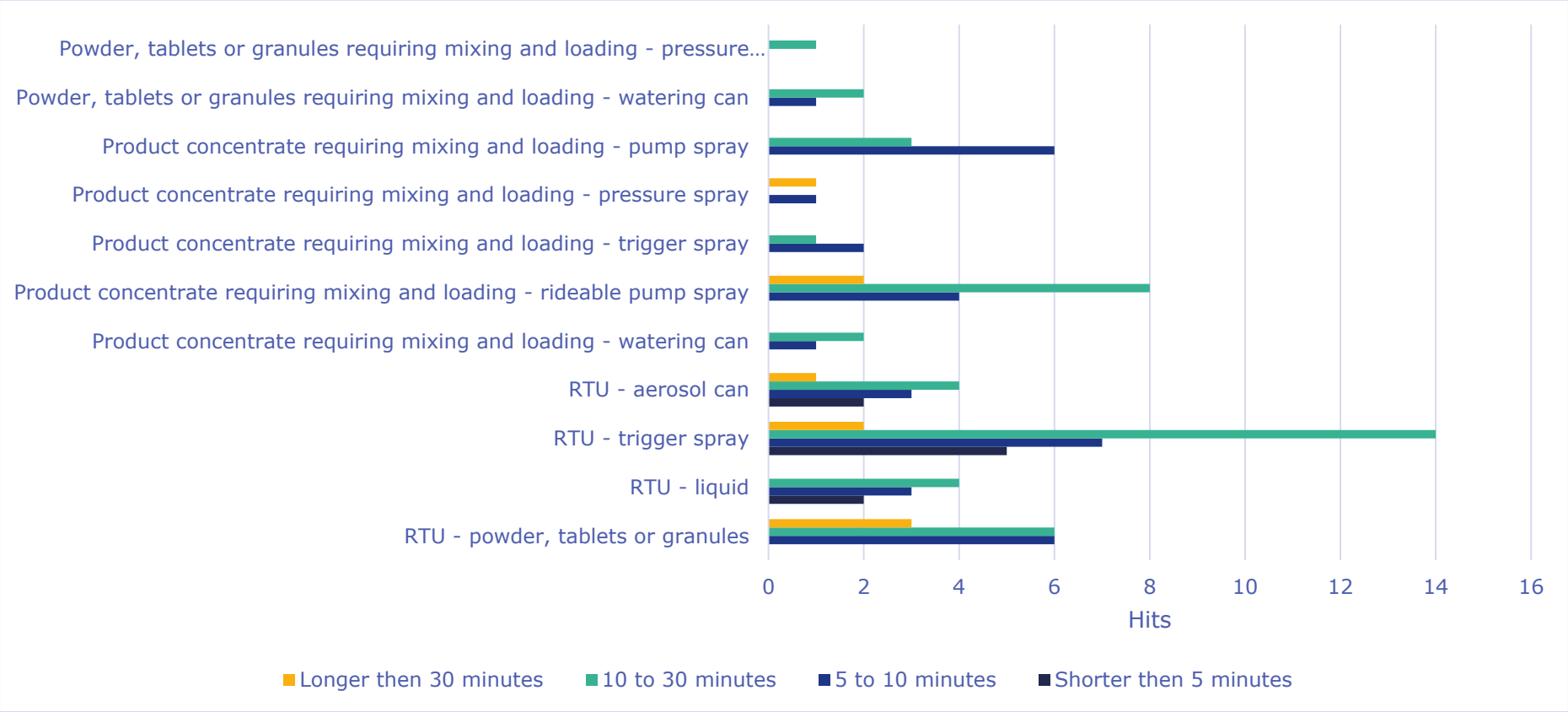
B17 – How long are you using the product each time you apply it?
Answered: 94



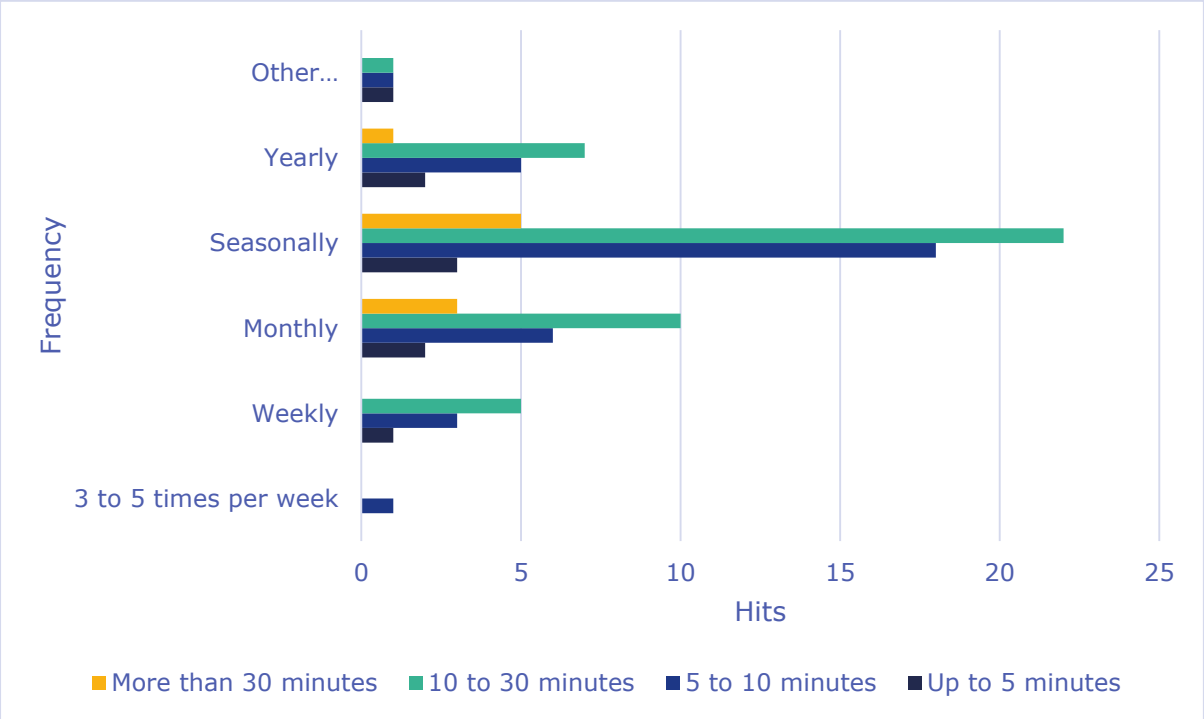
B18 – Frequency of use per application type



B19 – Duration of use per application type



B20 – Frequency of use versus duration of use



B21 – Time of application versus size of (kitchen) garden

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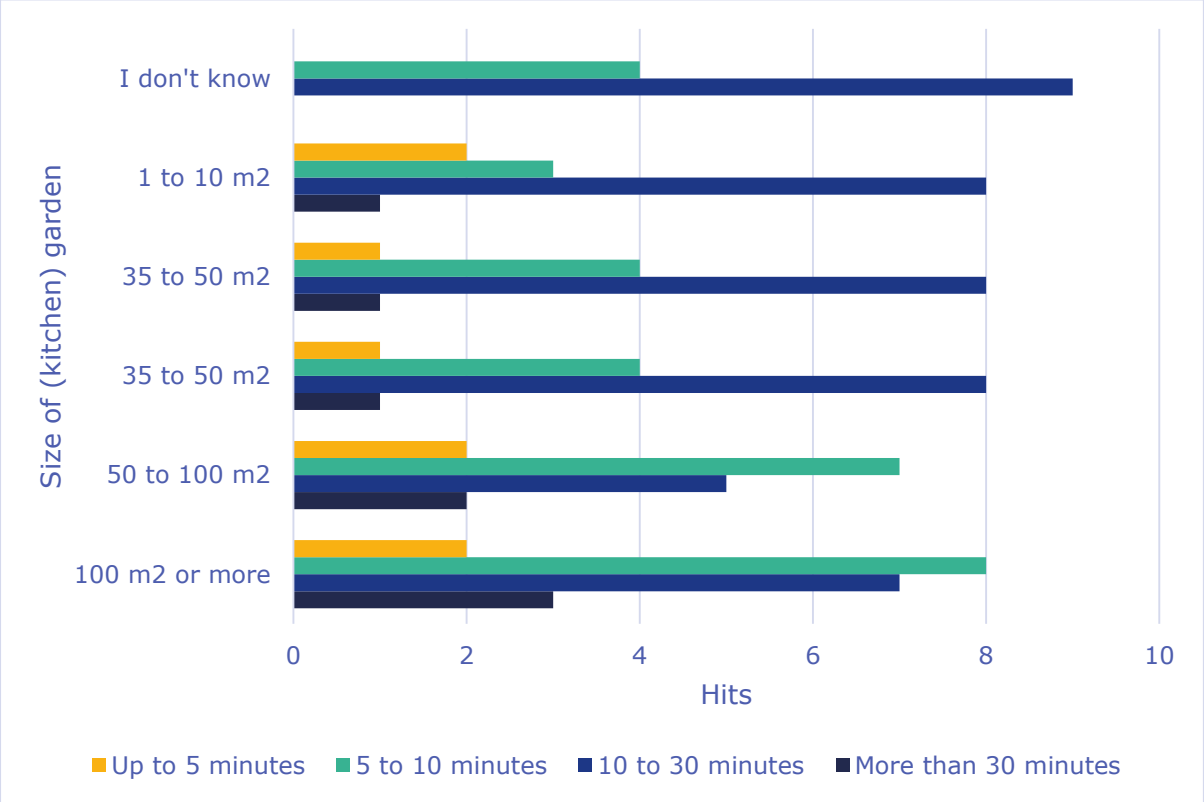
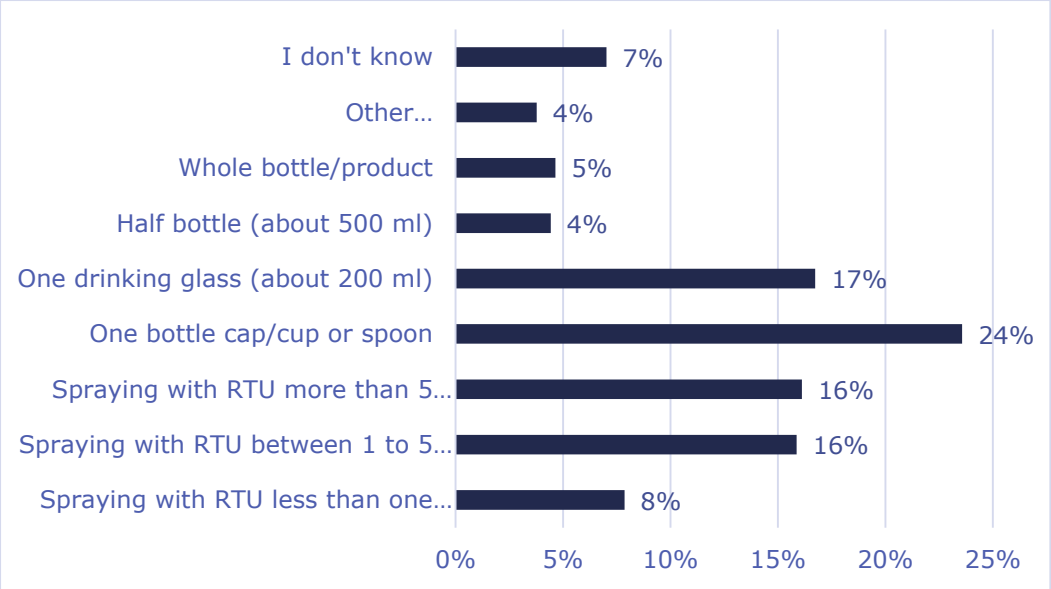
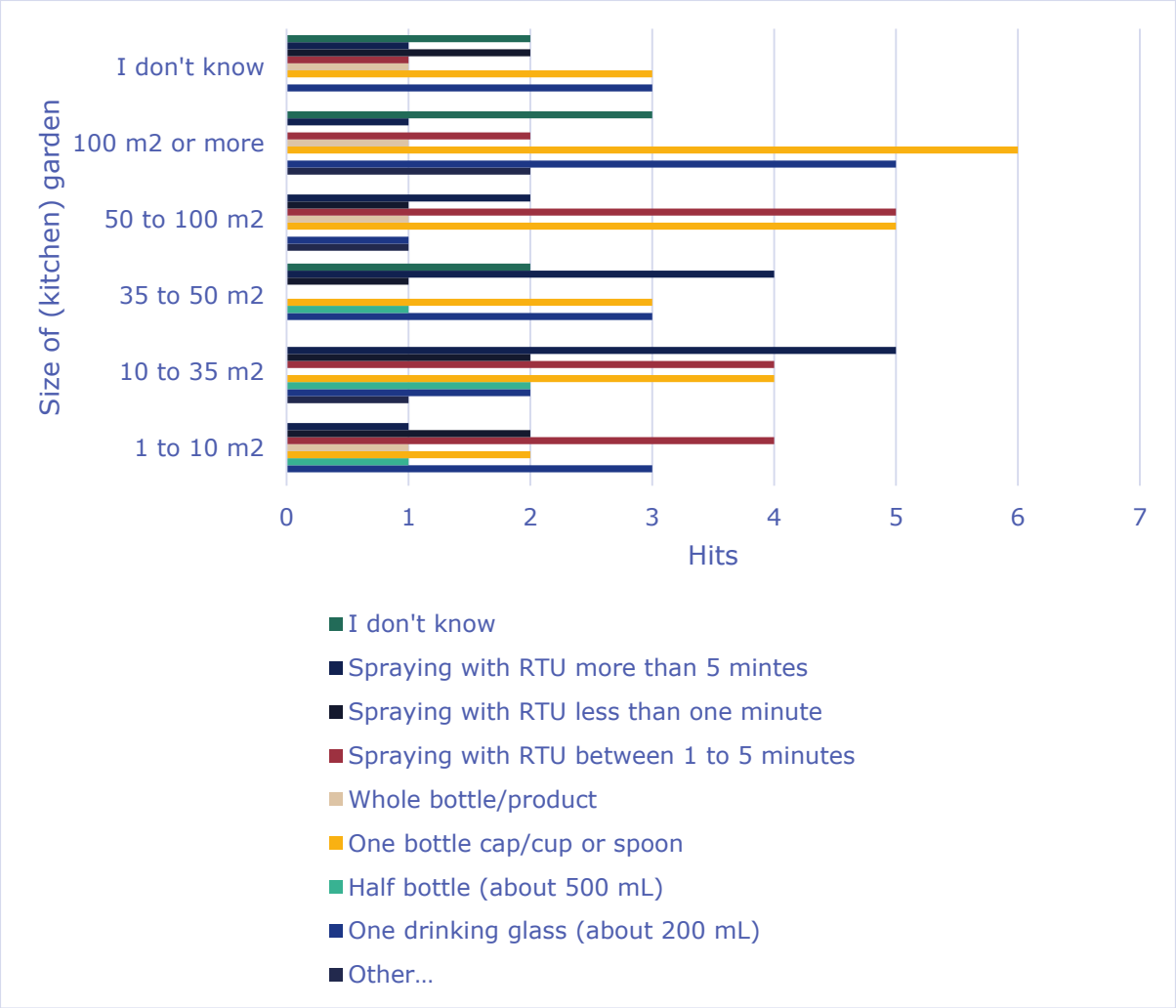


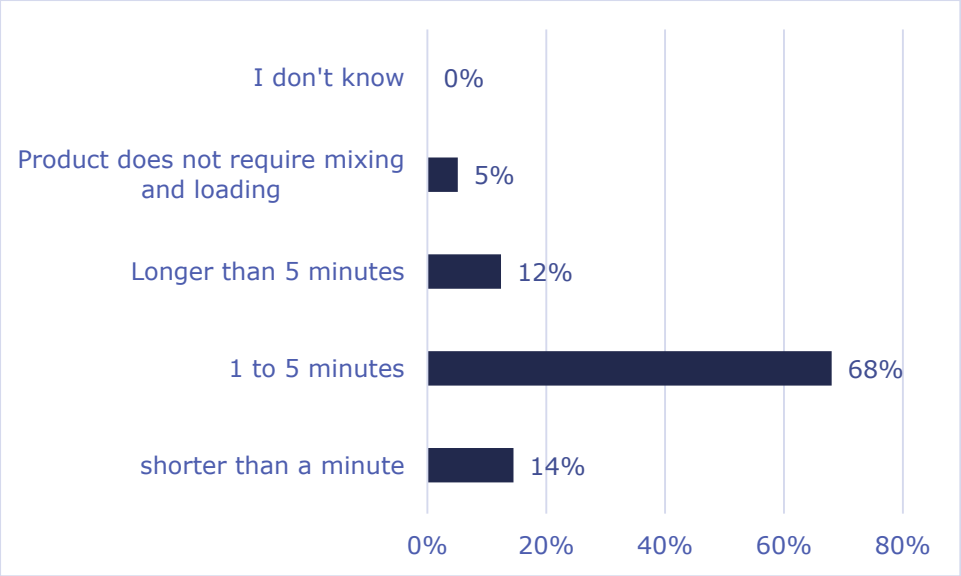
B22 – One a day of use, how much do you apply in case of a RTU product?
Answered: 94



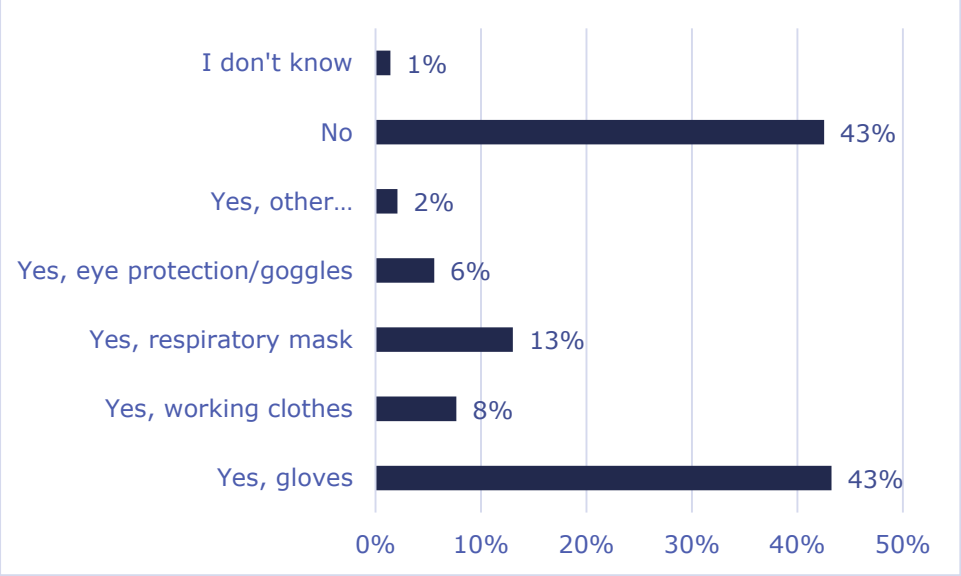
B23 – Amount used per size of (kitchen) garden



B24 – If the product requires mixing and loading, how much time does that consume?
Answered: 33



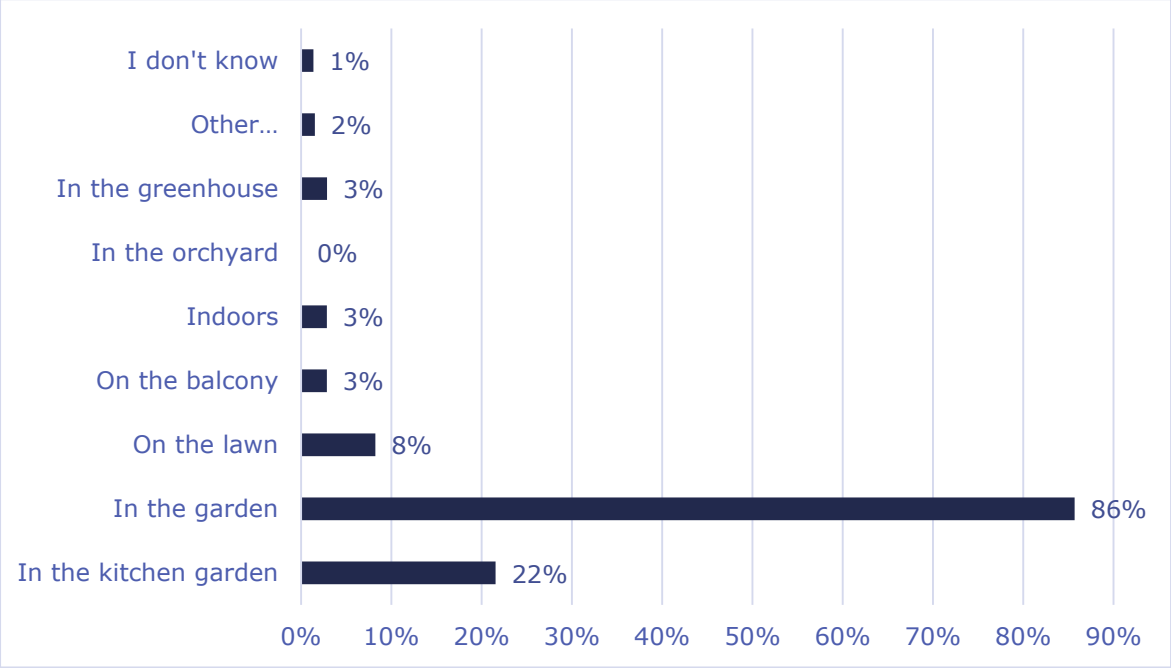
B25 – Do you wear any protective gear?
Answered: 94



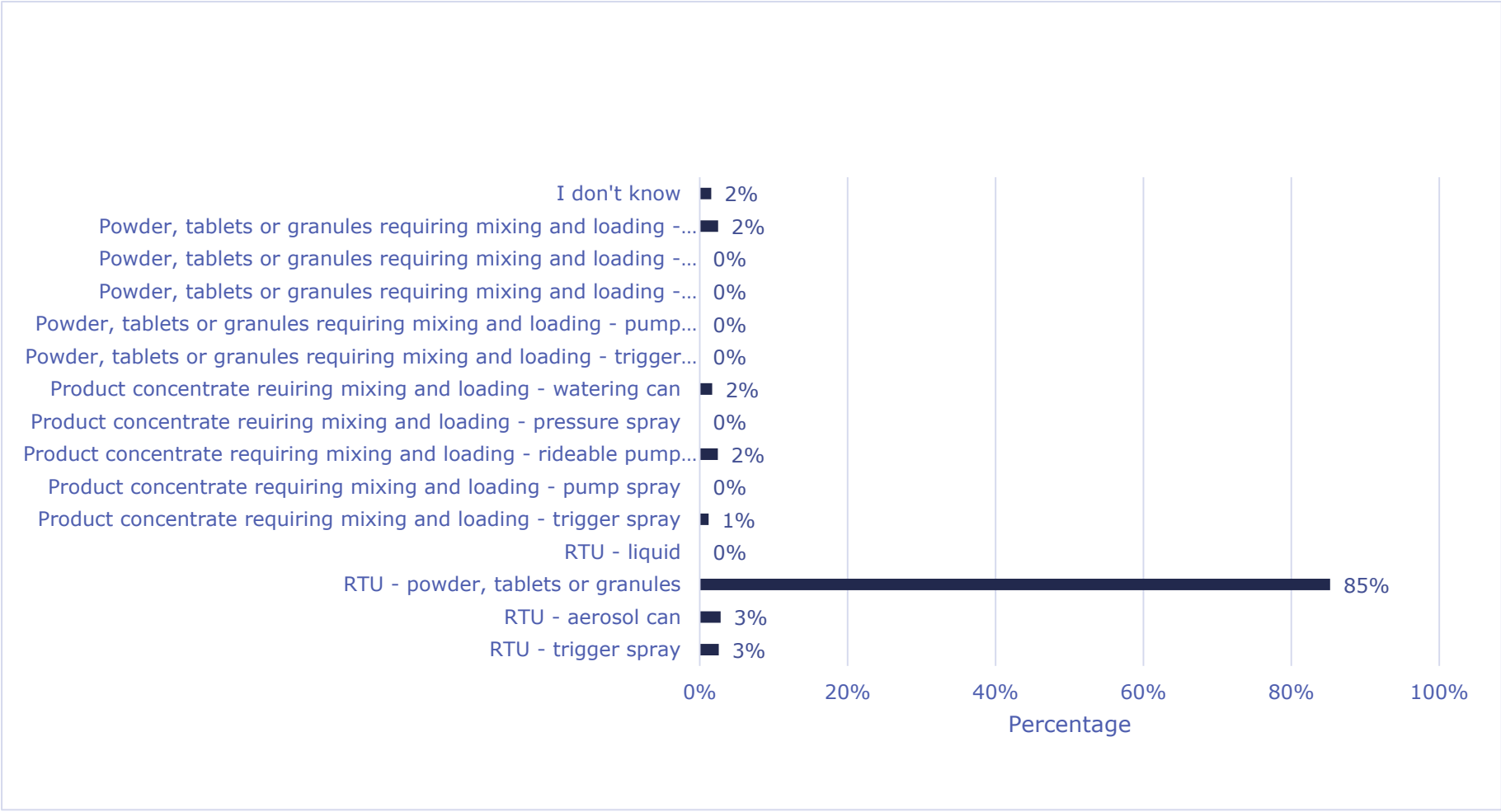
7.4 Slimicide

B26 – Can you specify where you apply slimicide?

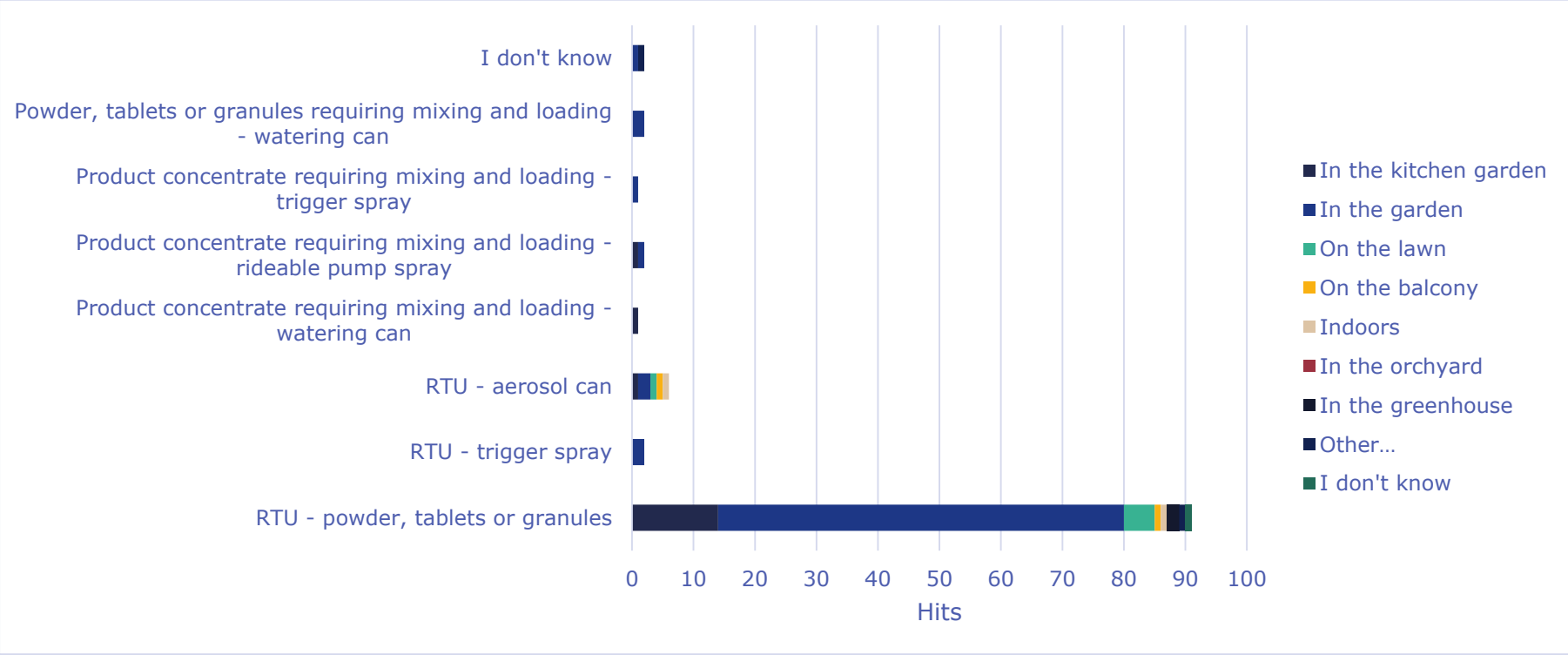
Answered: 80



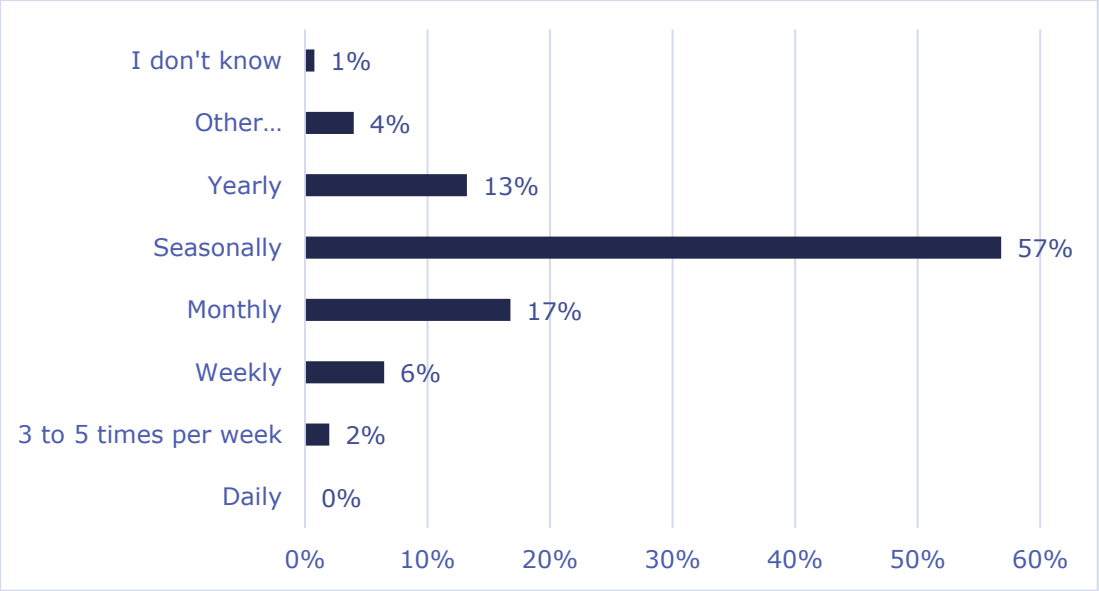
B27 – Can you specify what application type you use?
Answered: 80



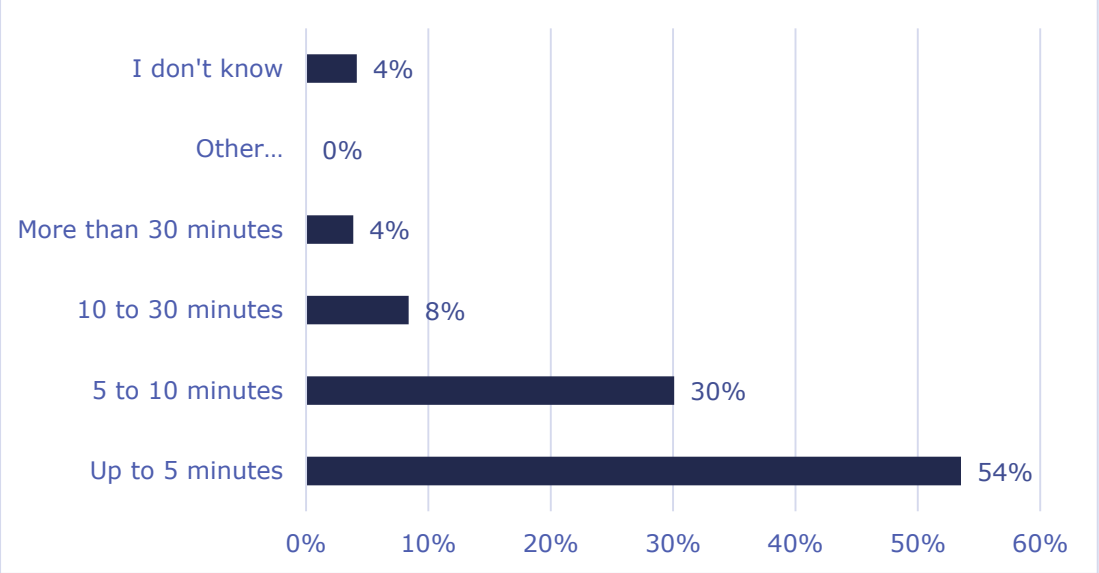
B28 – Location of use per application type



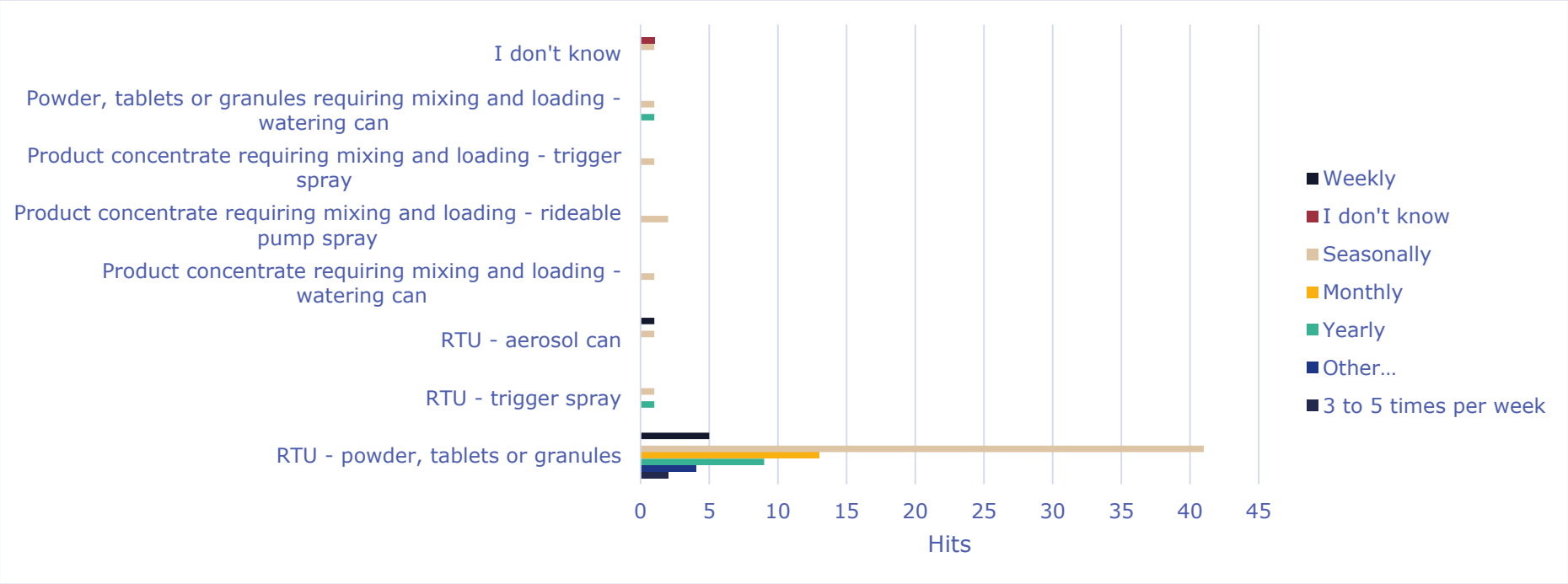
B29 – How often do you use that product?
Answered: 80



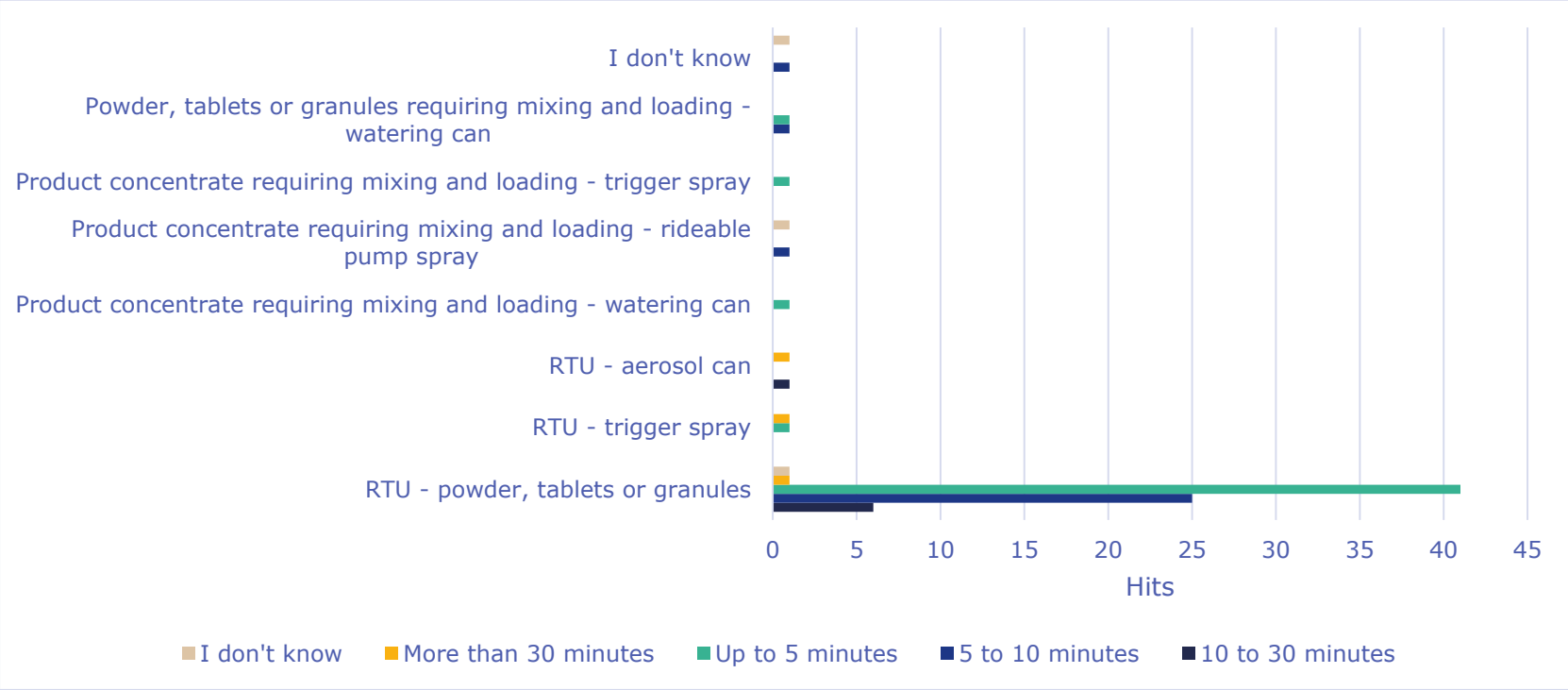
B30 – How long are you using the product each time you apply it?
Answered: 80



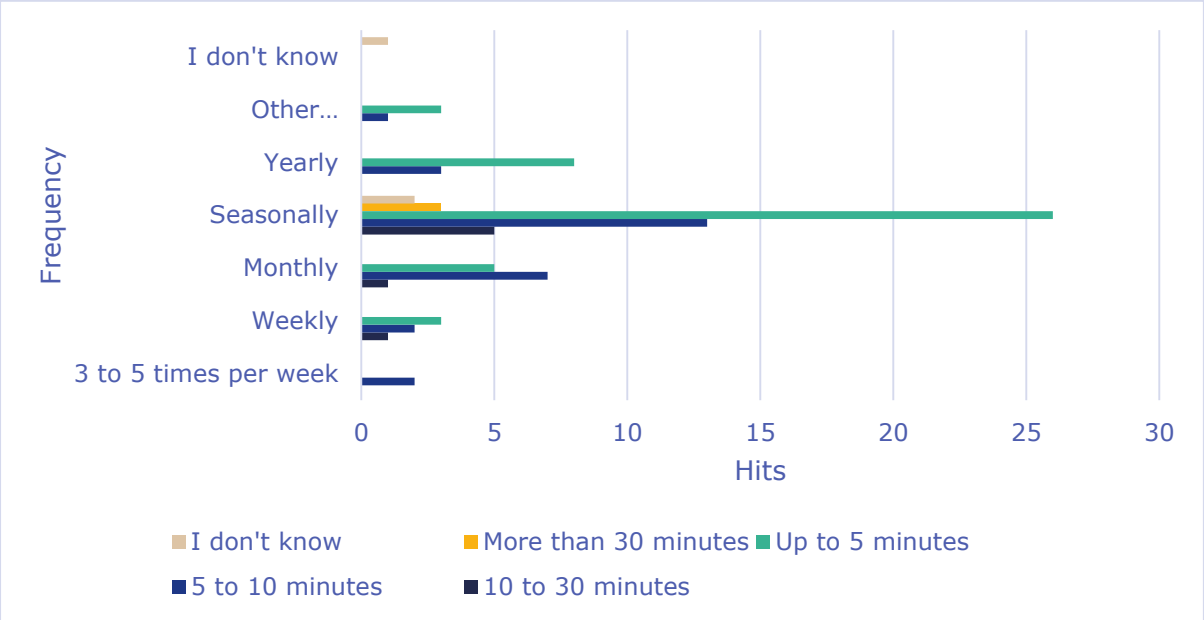
B31 – Frequency of use per application type



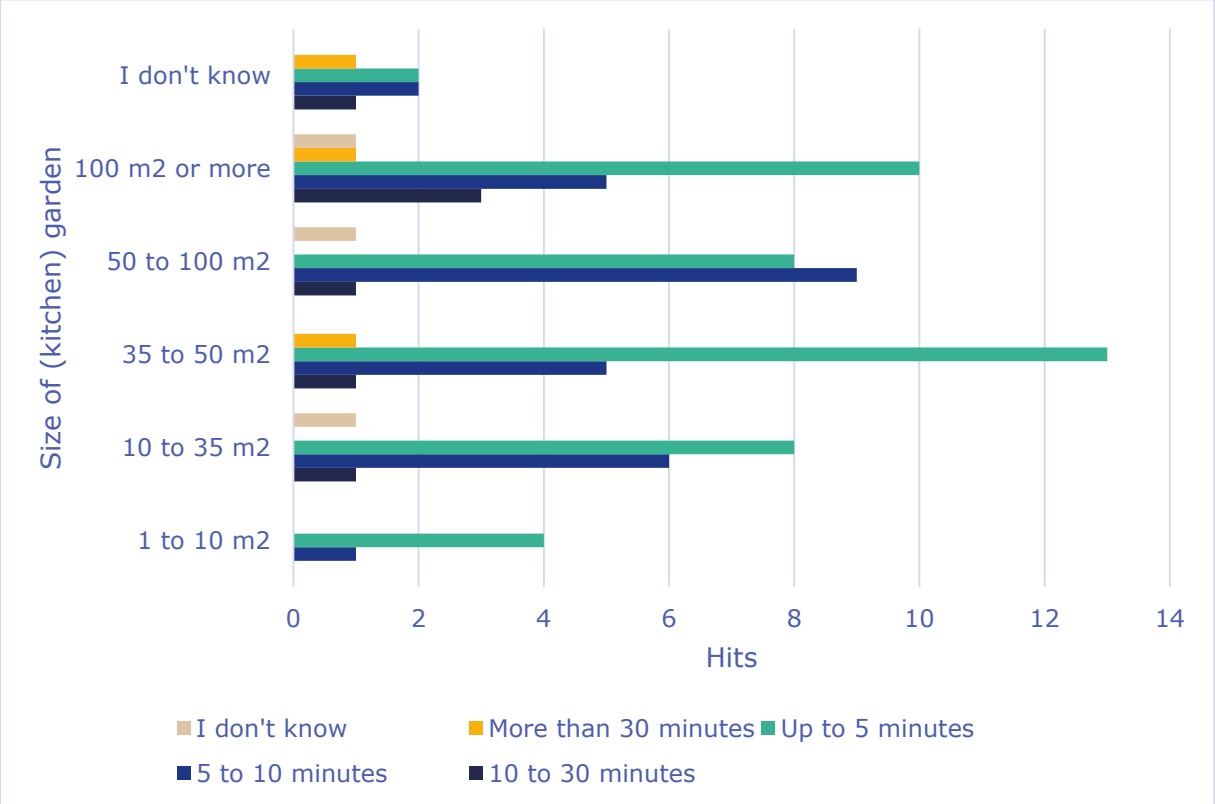
B32 – Duration of use per application type



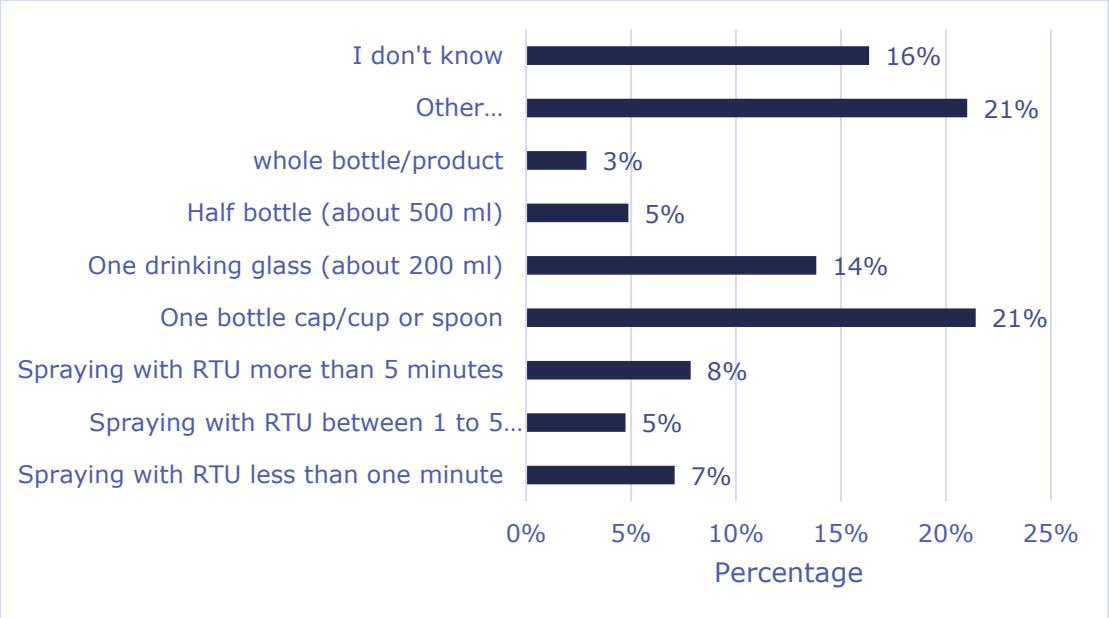
B33 – Frequency of use versus duration of use



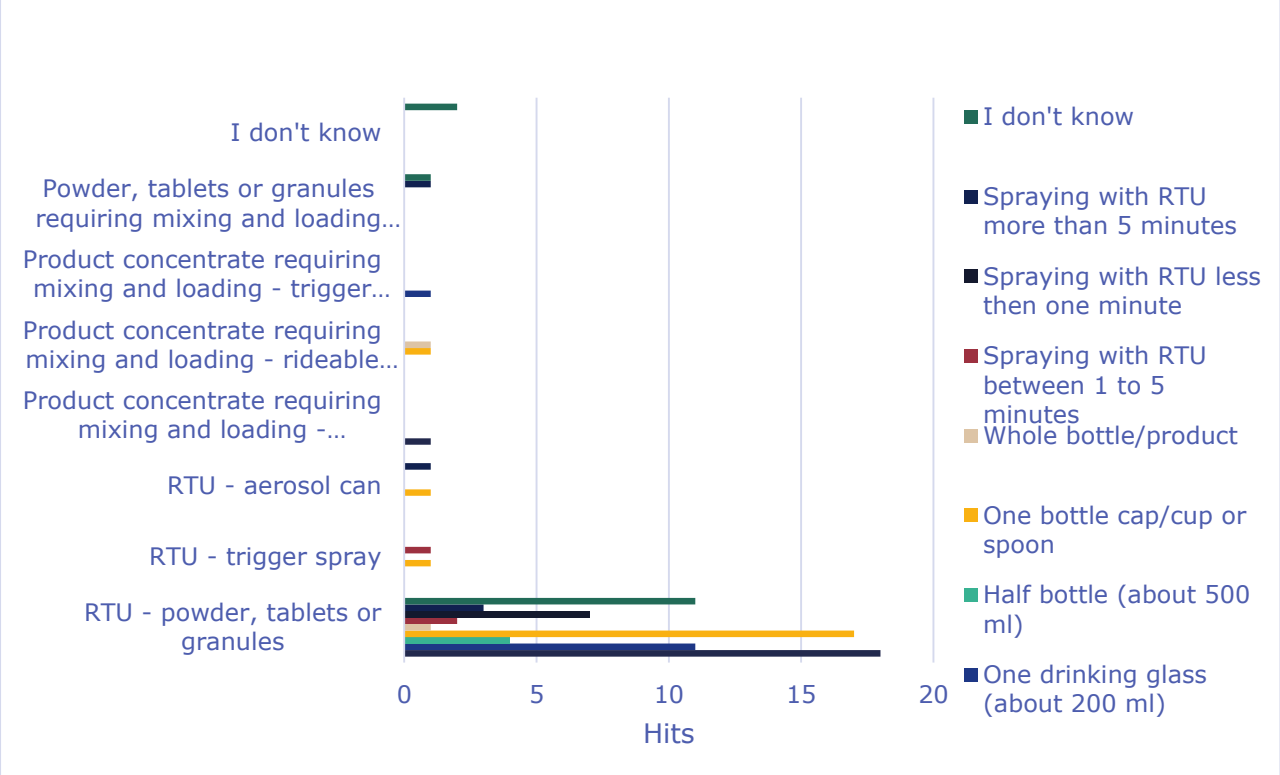
B34 – Time of application per size of (kitchen) garden



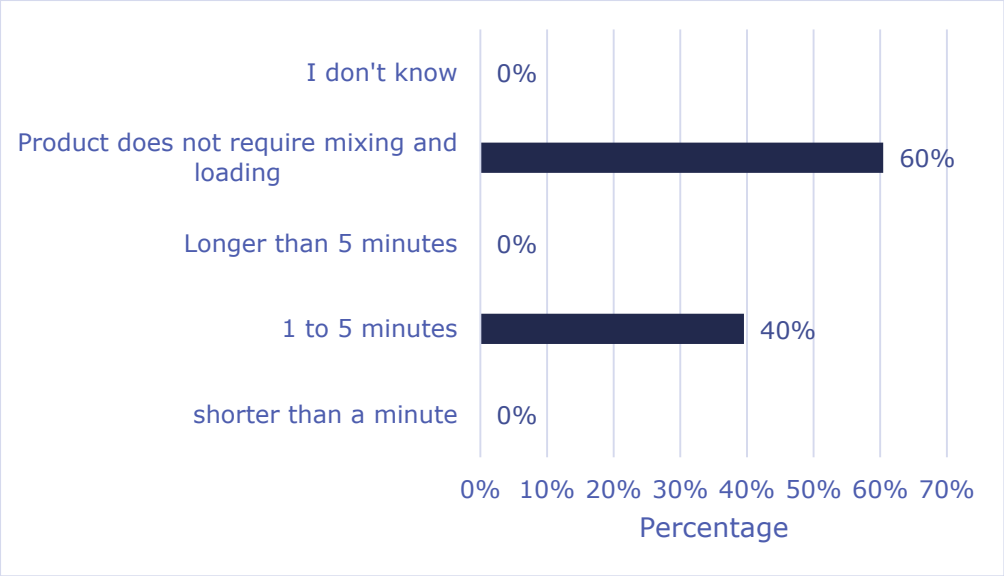
B35 – One a day of use, how much do you apply in case of a RTU product?
Answered: 80



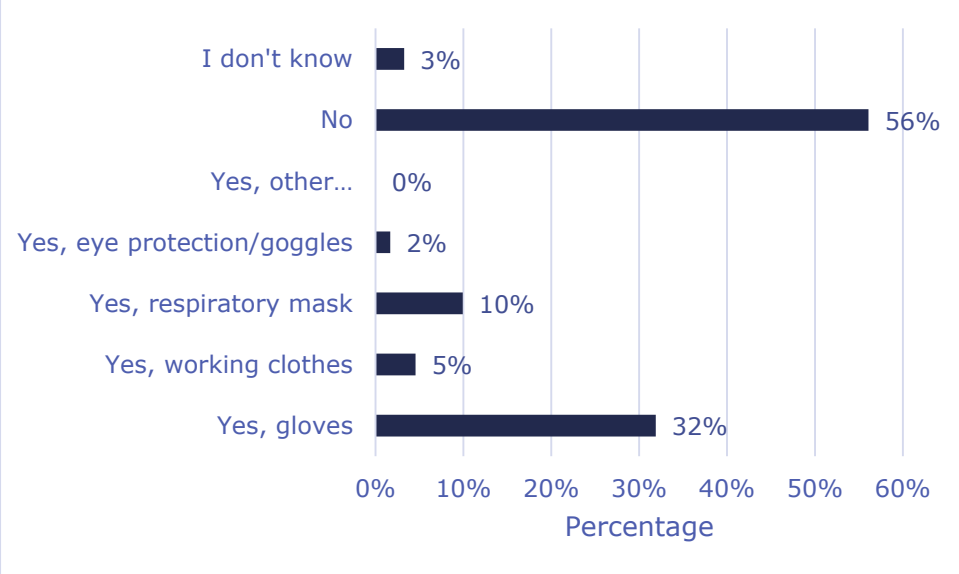
B36 – Amount used per type of RTU product



B37 – If the product requires mixing and loading, how much time does that consume?
Answered: 6

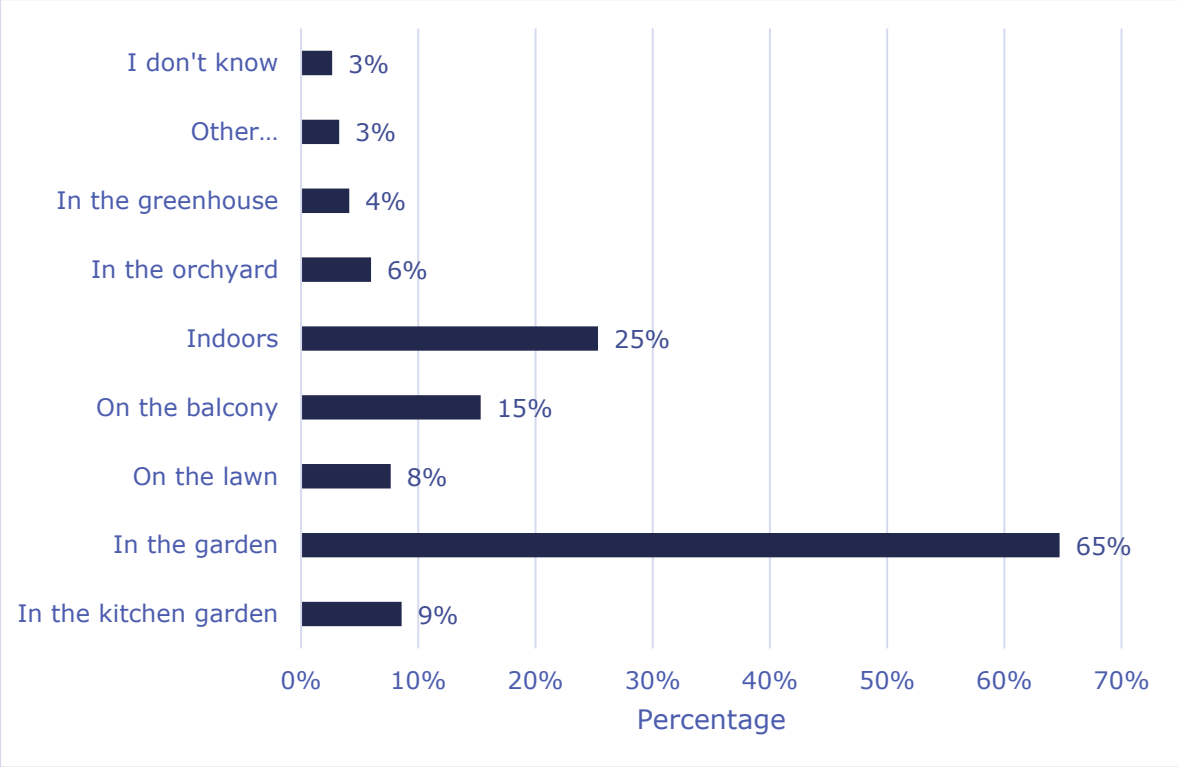


B38 – Do you wear any protective gear?
Answered: 80

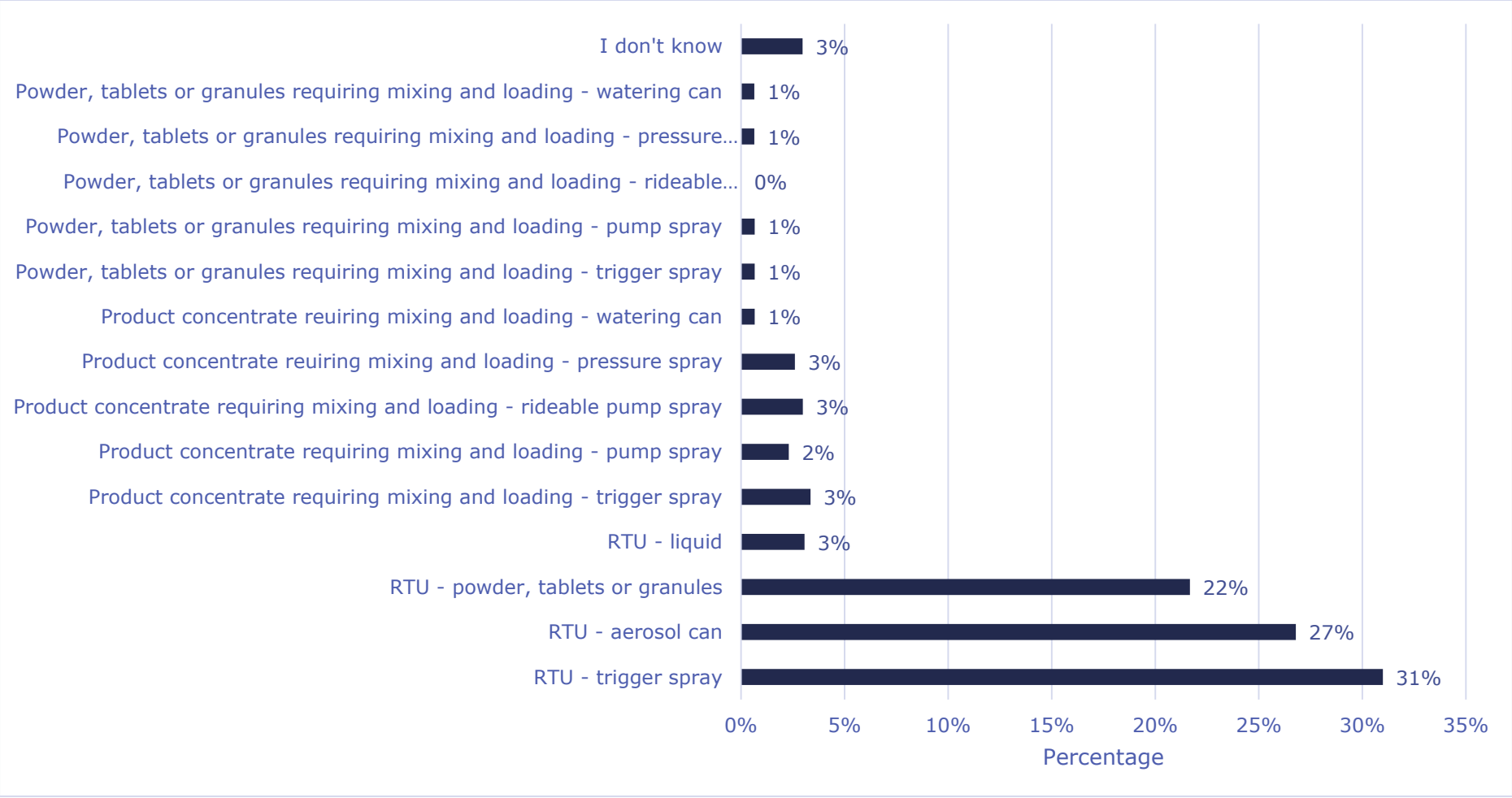


7.5 Insecticides against lice, moth and other pests

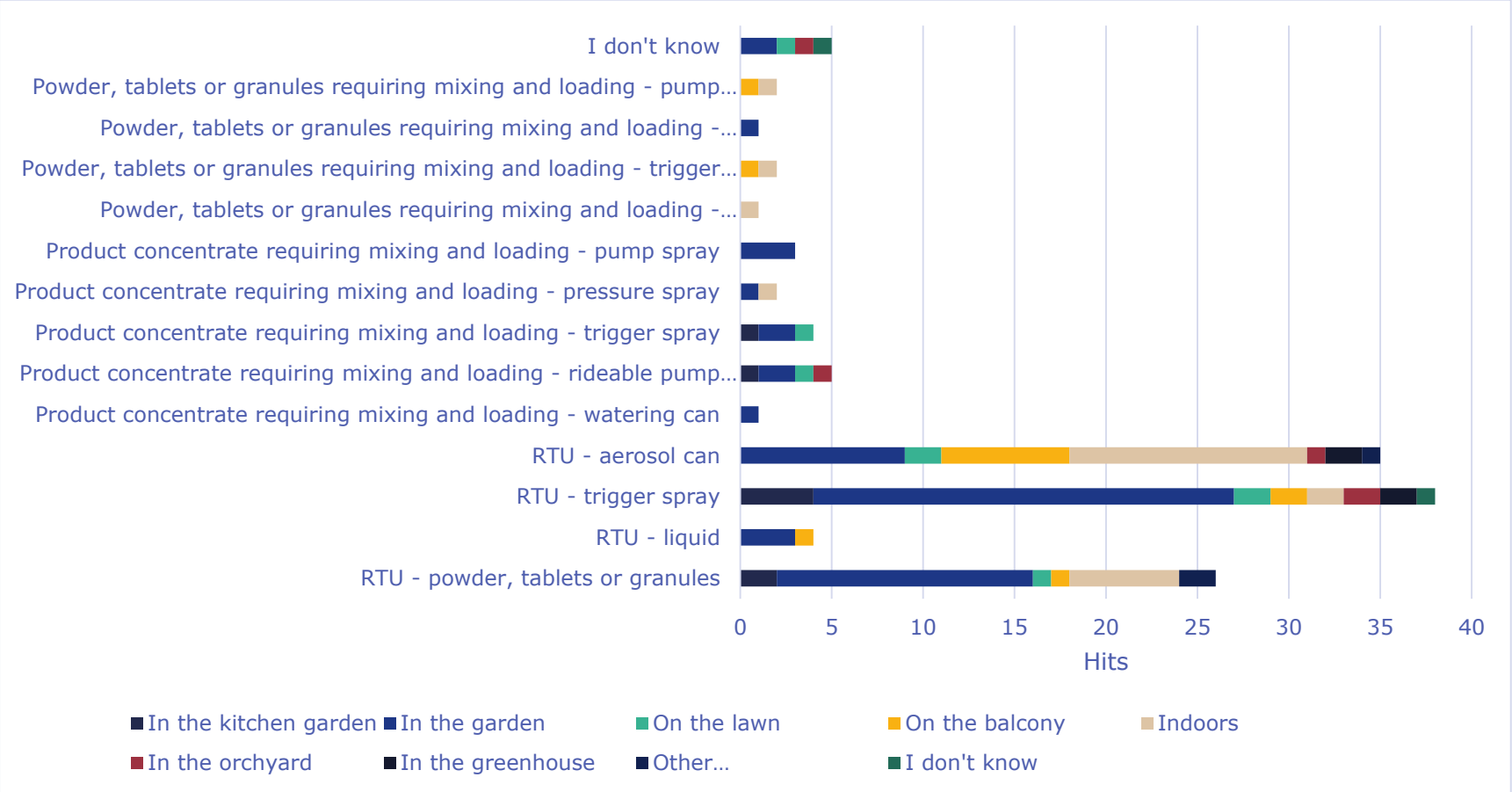
B39 – Can you specify where you apply pesticide against lice, moth and other pests?
Answered: 94



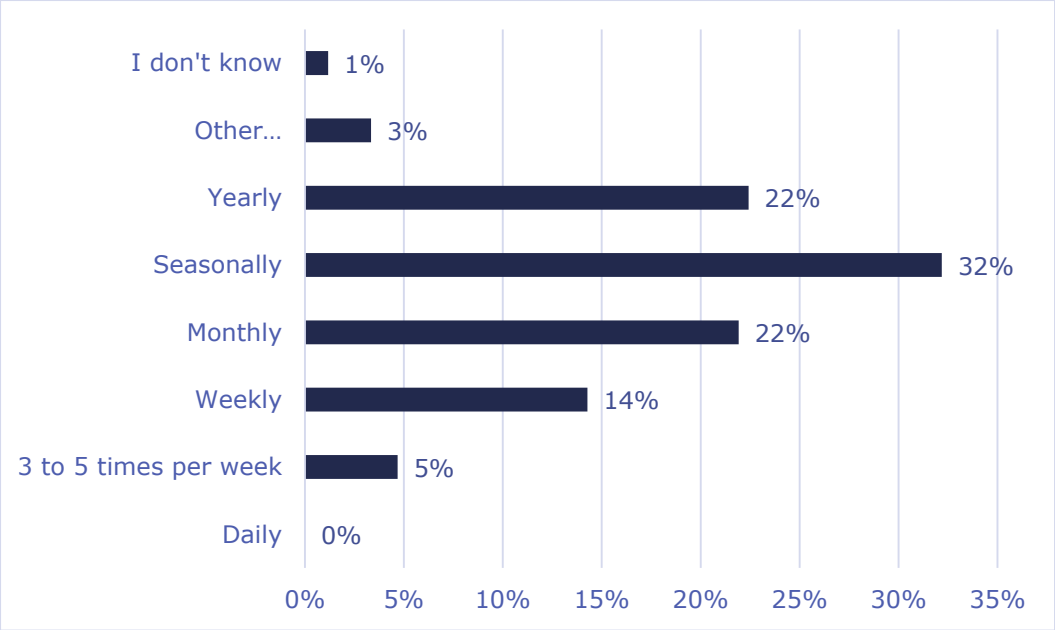
B40 – Can you specify what application type you use?
Answered: 94



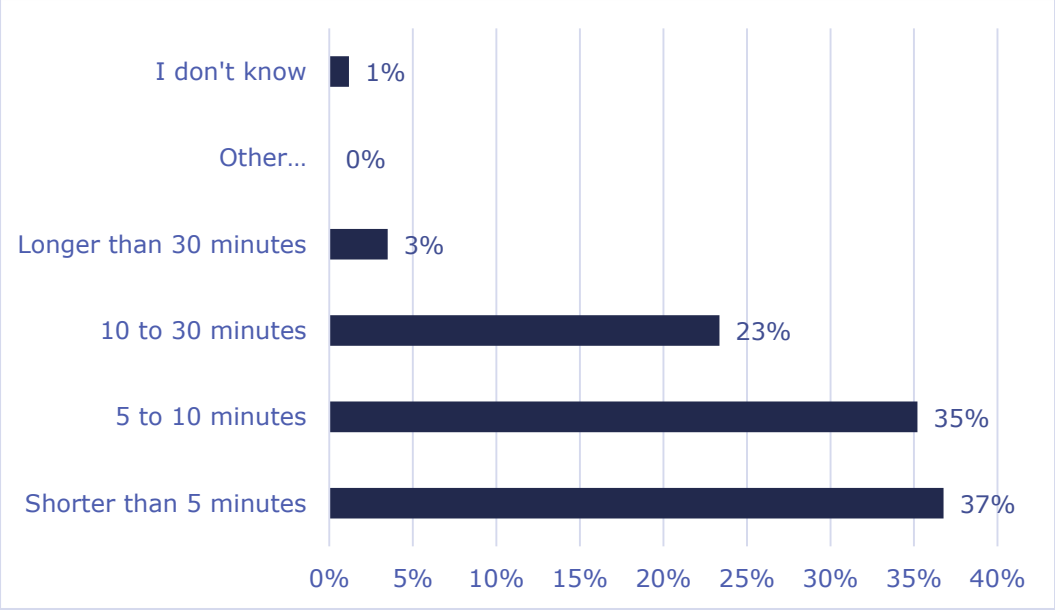
B41 – Location of use per application type



B42 – How often do you use insecticides?
Answered: 94



B43 – How long are you using the product each time you apply it?
Answered: 94



B44 – Frequency of use per application type

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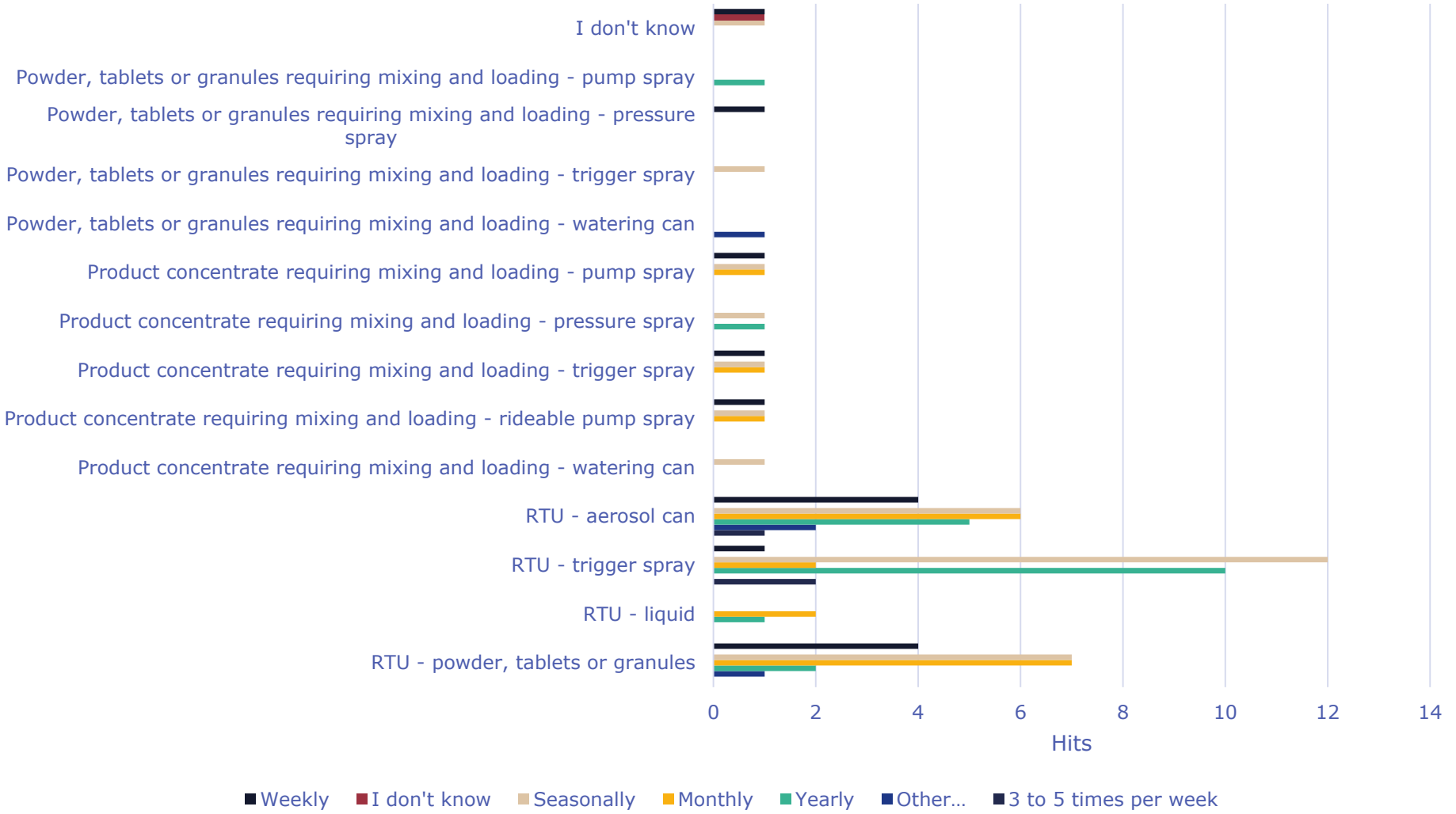
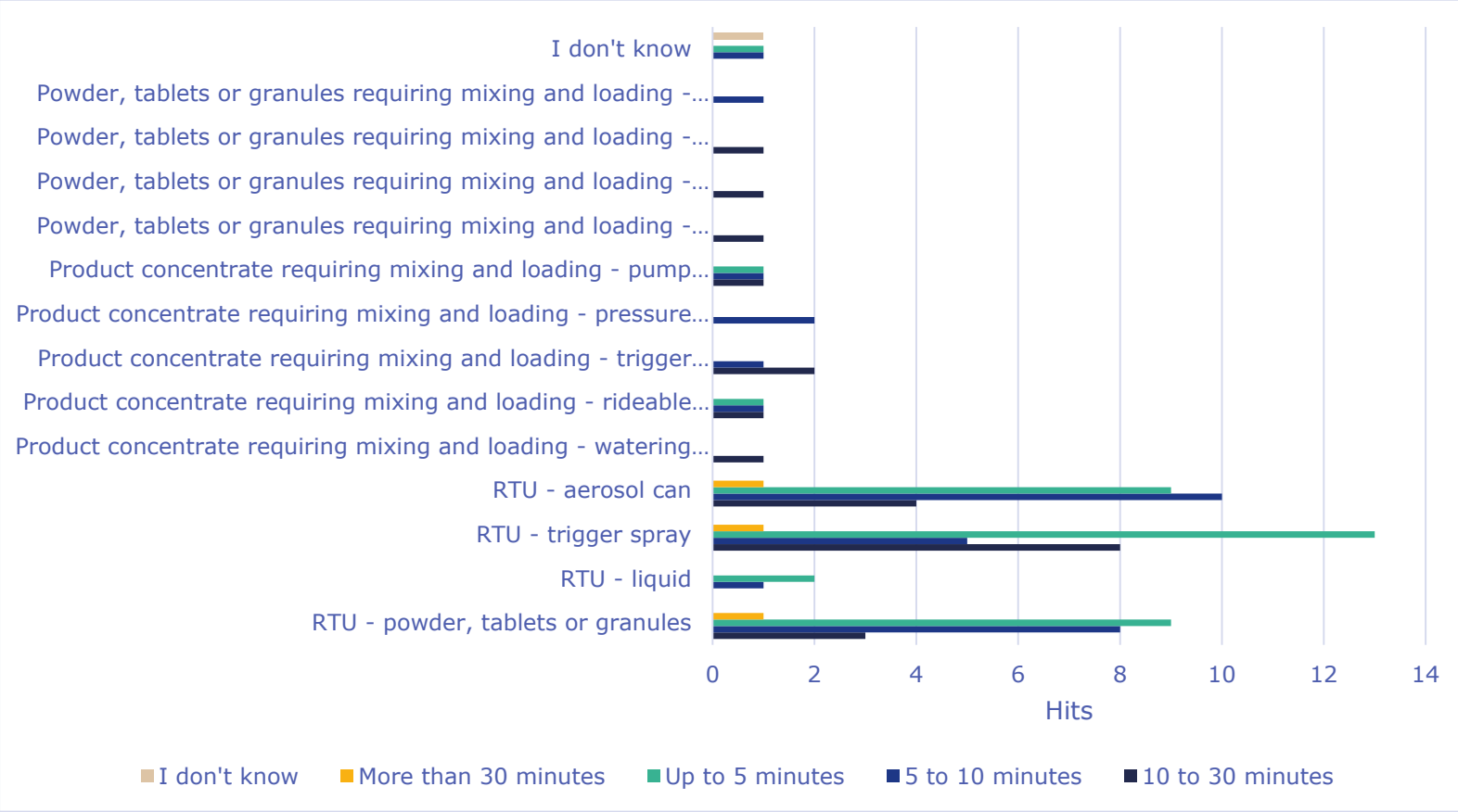
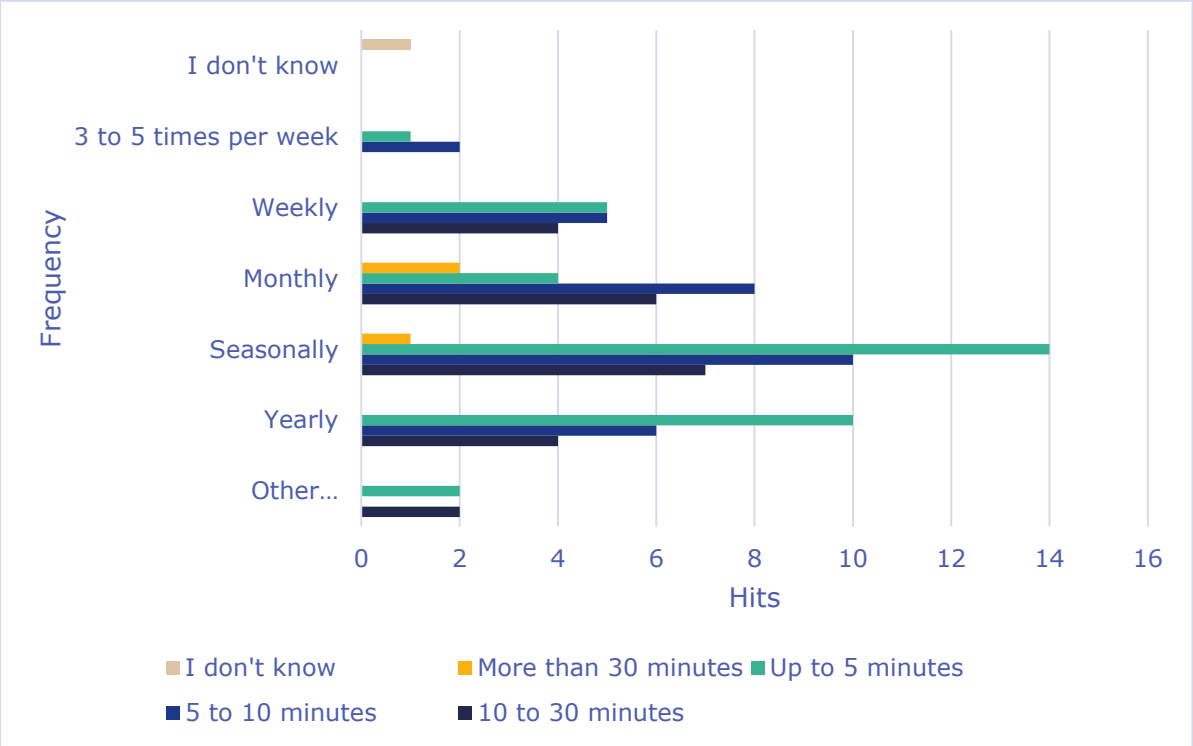


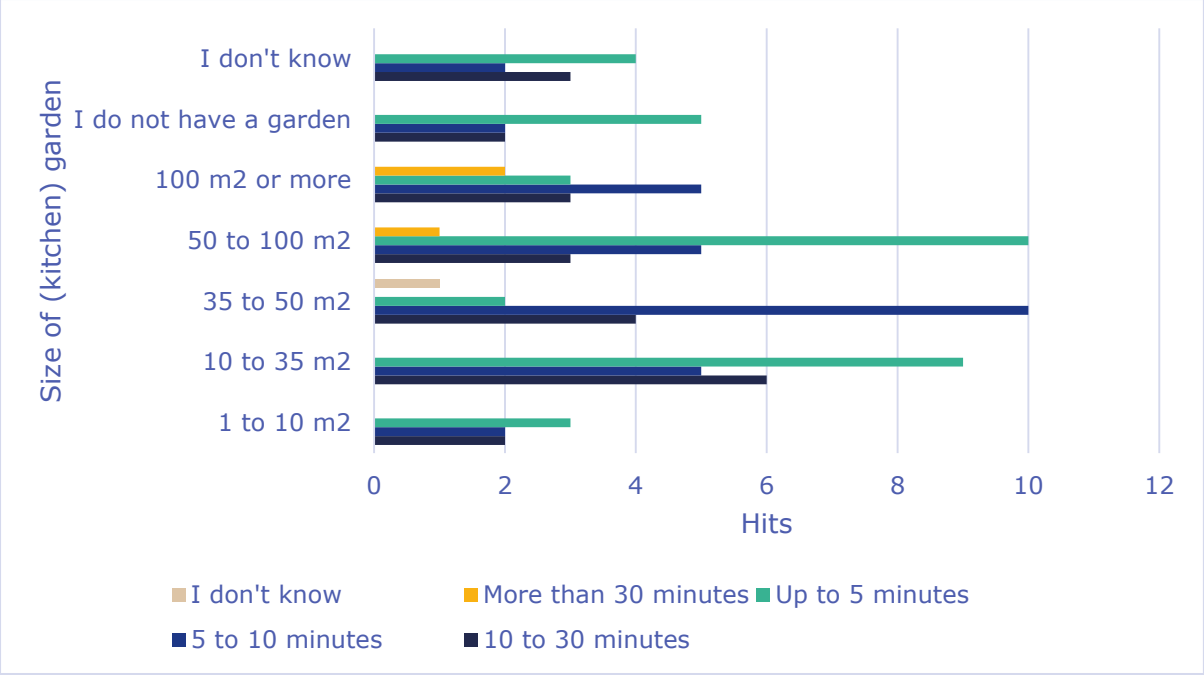
B45 – Duration of use per application type



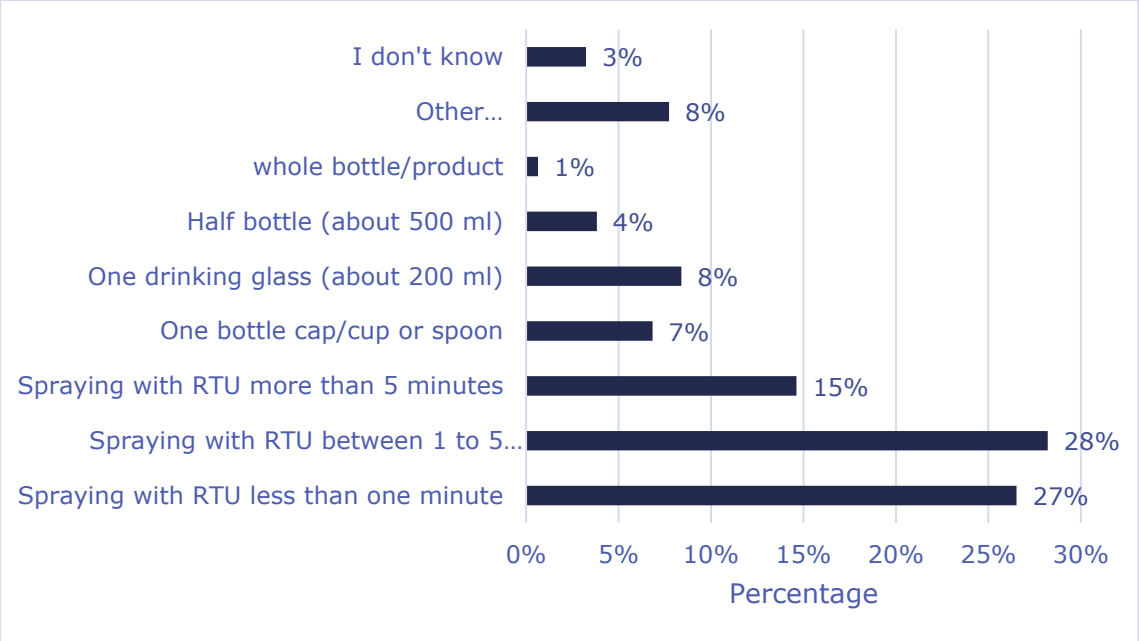
B46 – Frequency of use versus duration of use



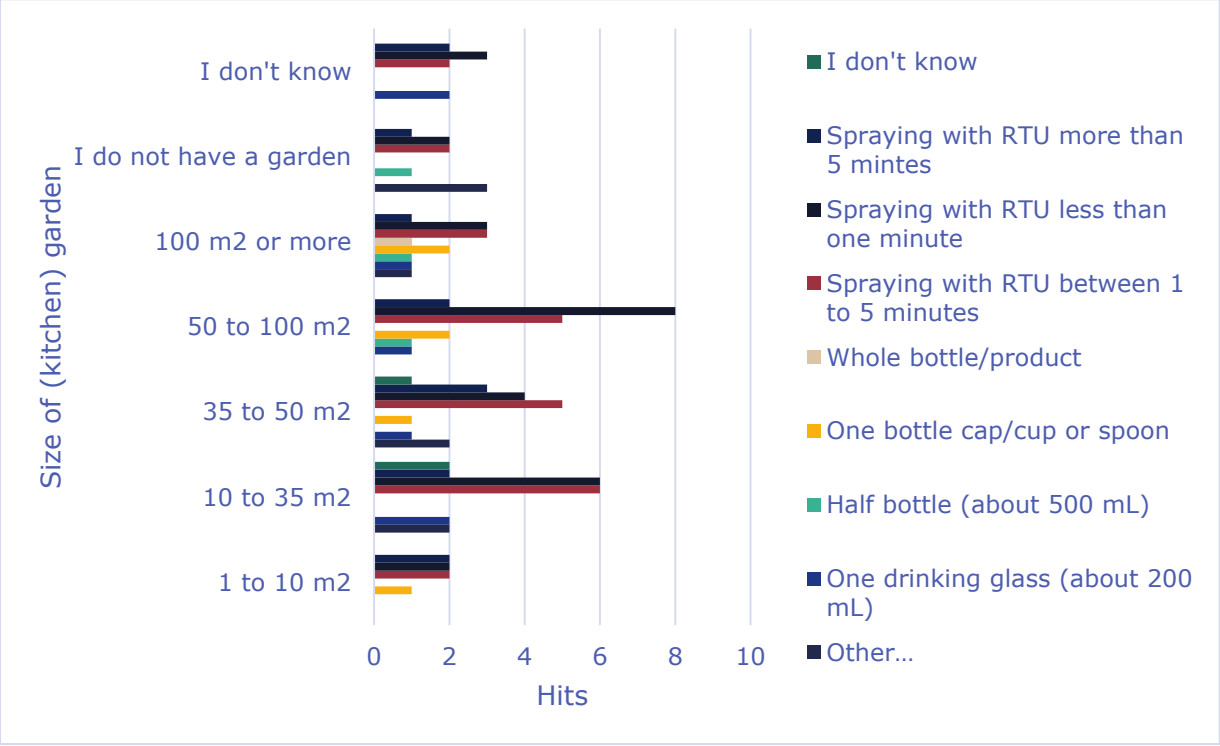
B47 – Time of application versus size of (kitchen) garden



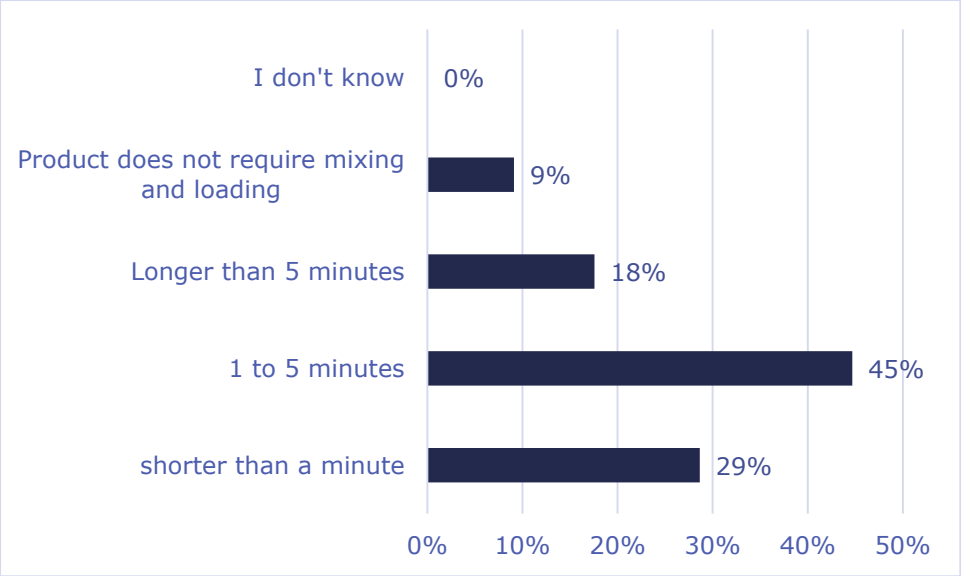
B48 – One a day of use, how much do you apply in case of a RTU product?
Answered: 94



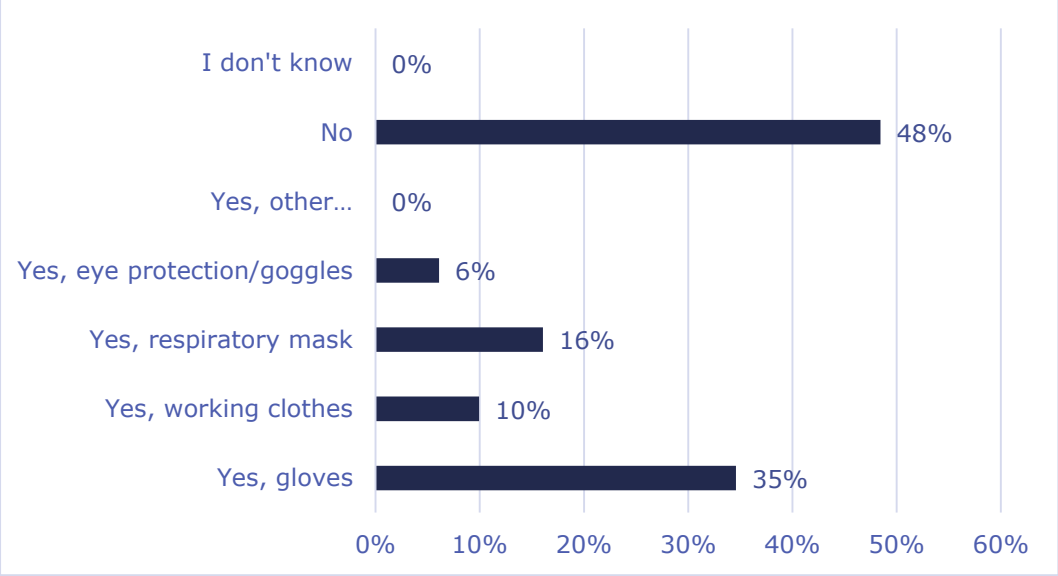
B49 – Amount used per size of (kitchen) garden



B50 – If the product requires mixing and loading, how much time does that consume?
Answered: 14

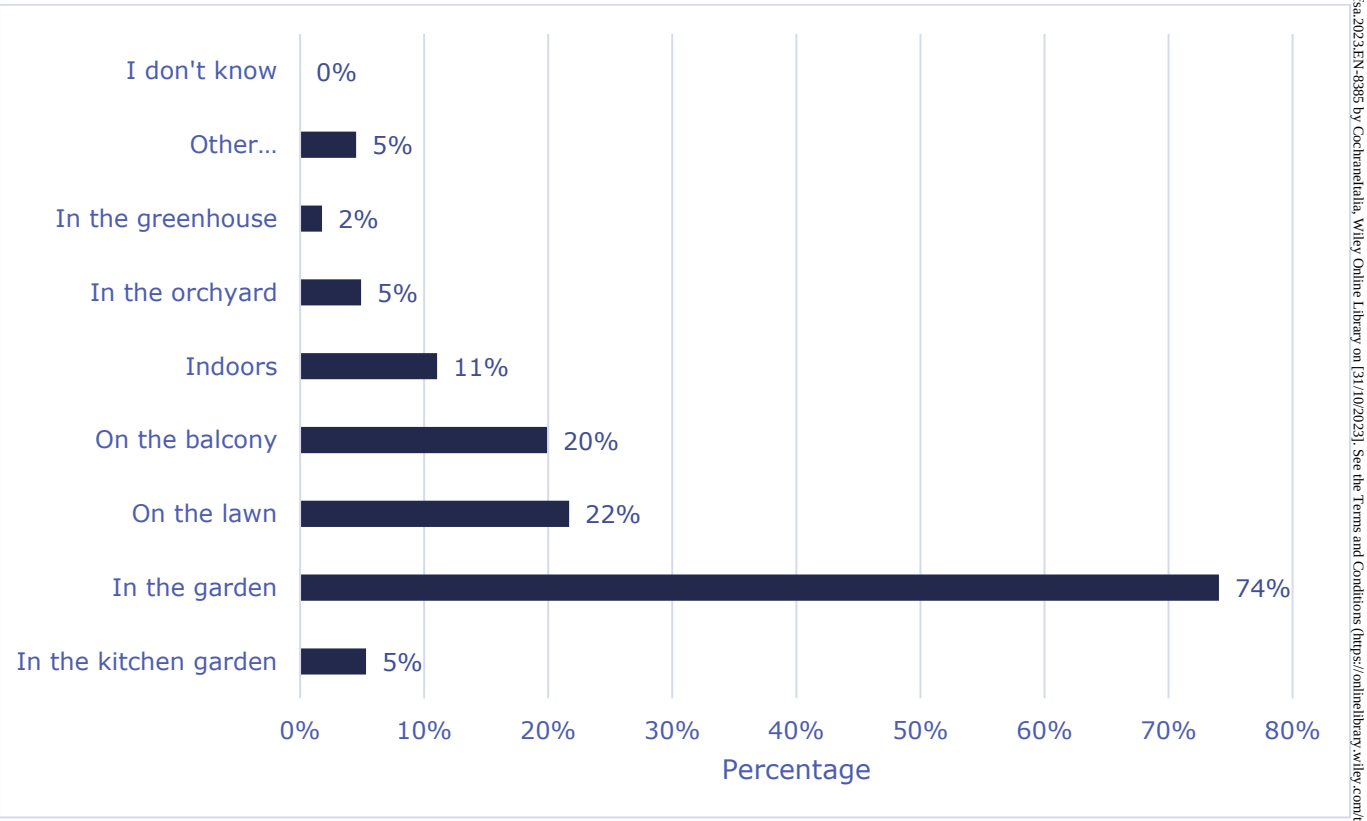


B51 – Do you wear any protective gear?
Answered: 94

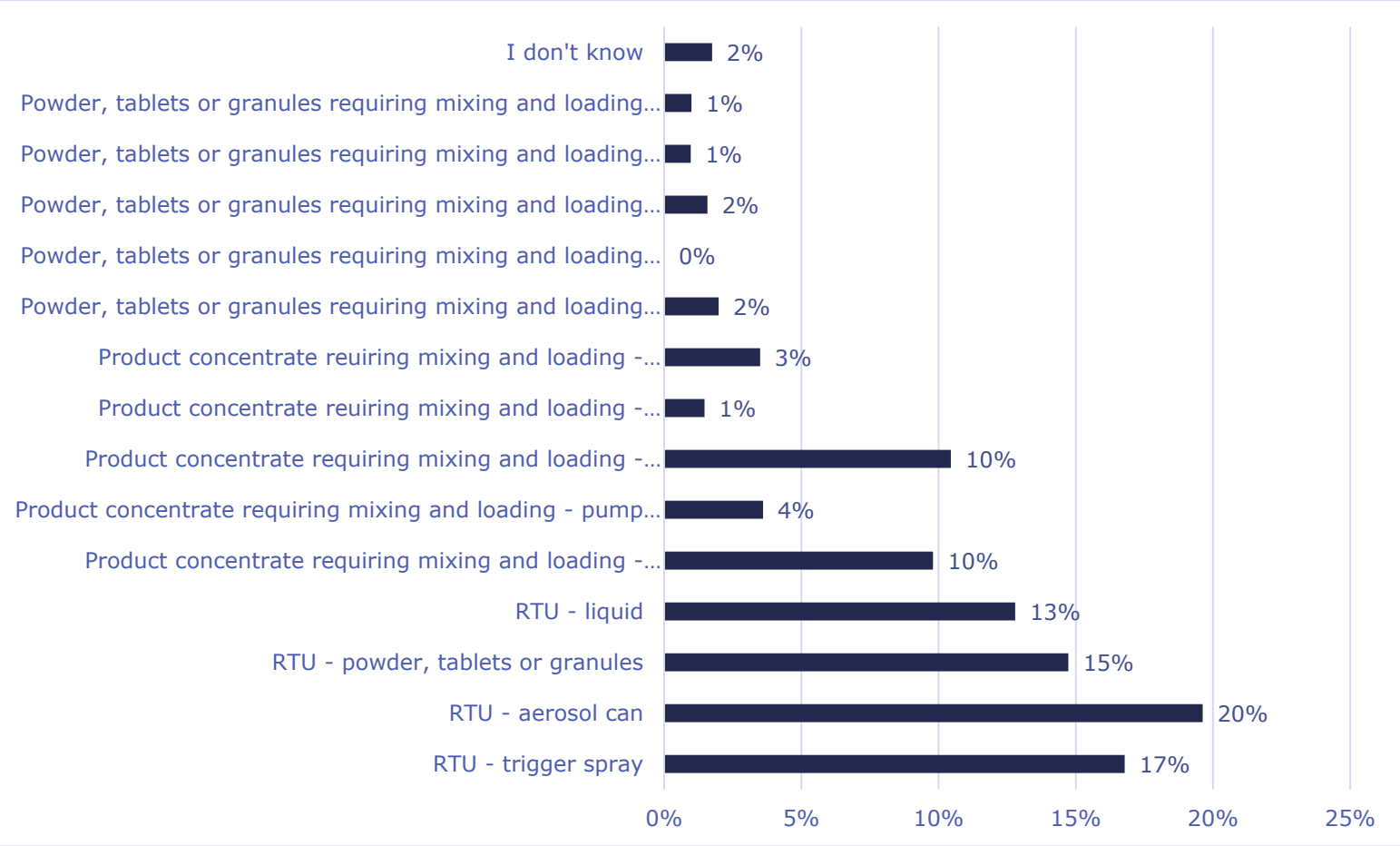


7.6 Treatment against moss, algae, fungi on pavement

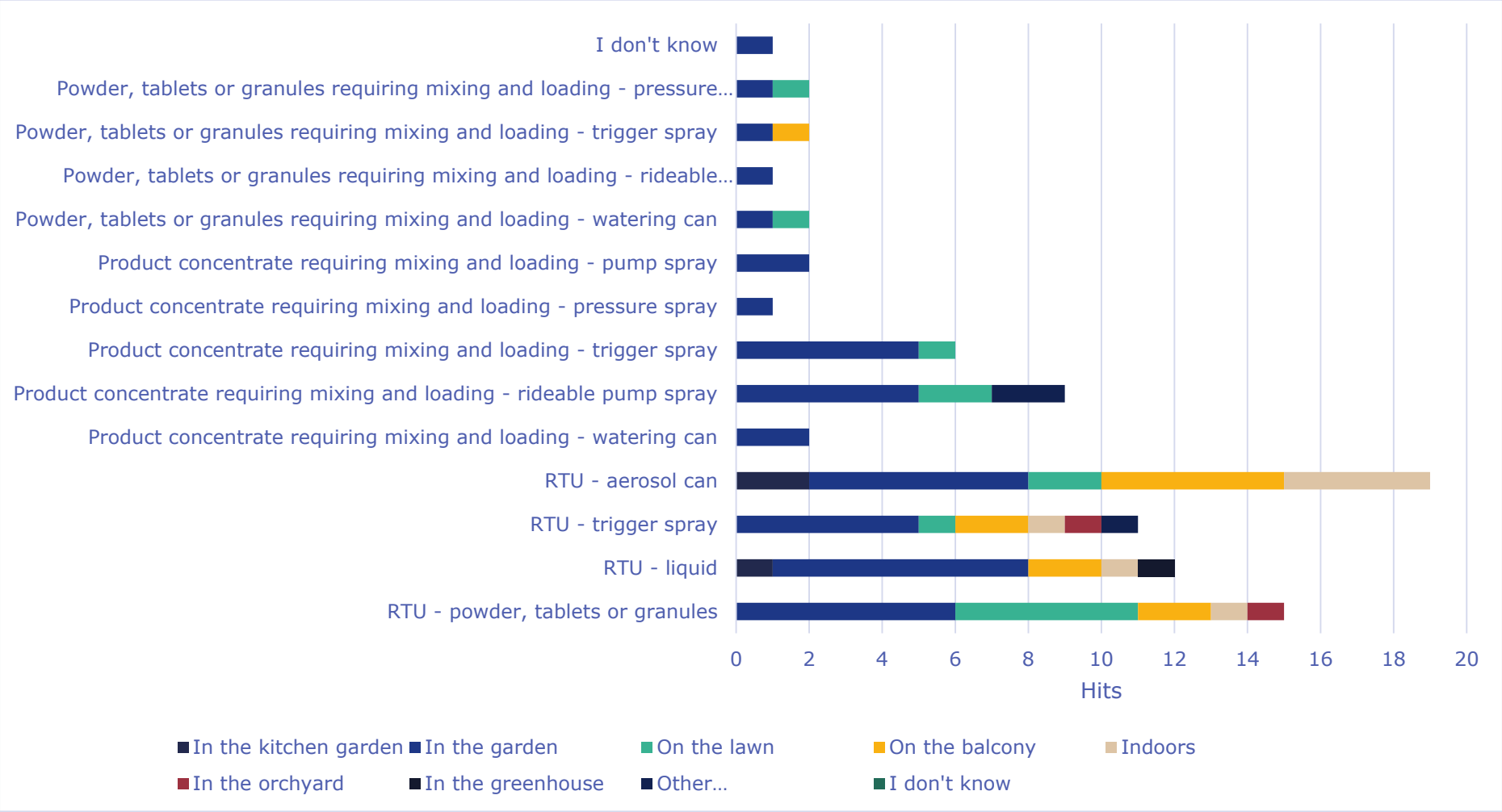
B52 – Can you specify where you apply products for treatment against moss, algae, fungi on pavement?
Answered: 62



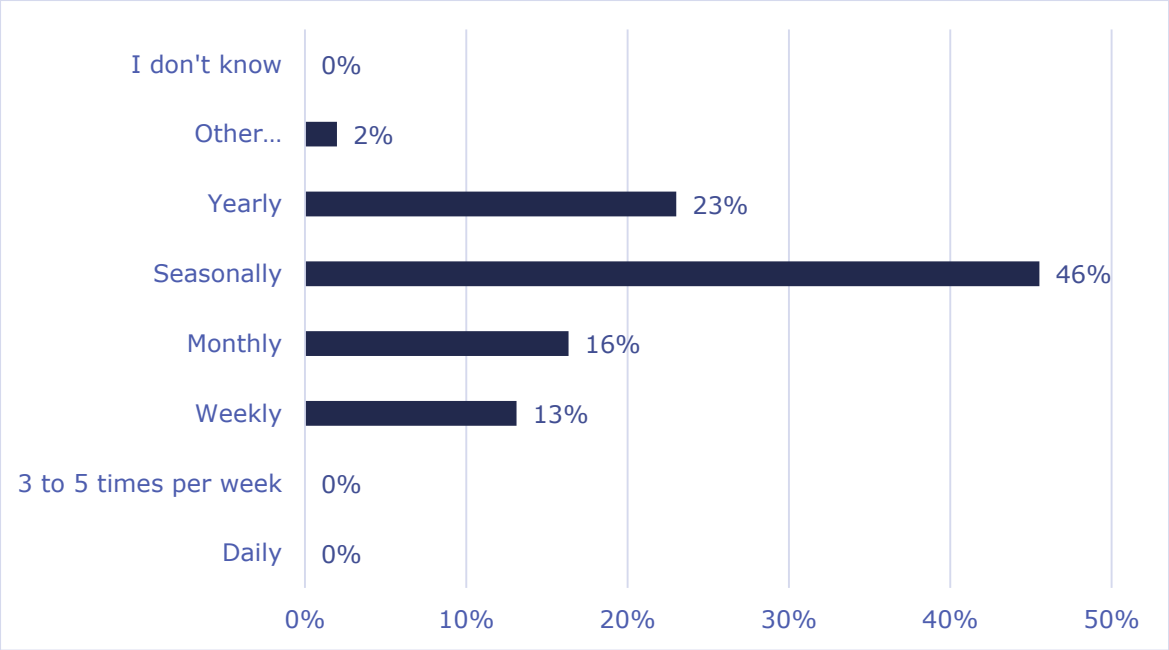
B53 – Can you specify what application type you use?
Answered: 62



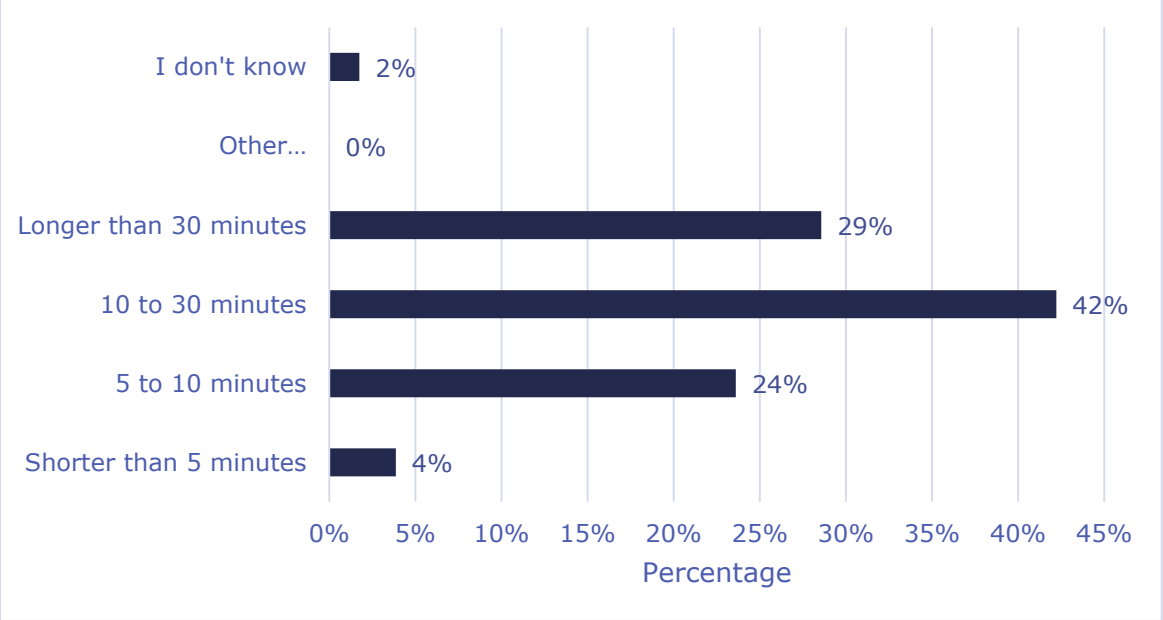
B54 – Location of use per application type



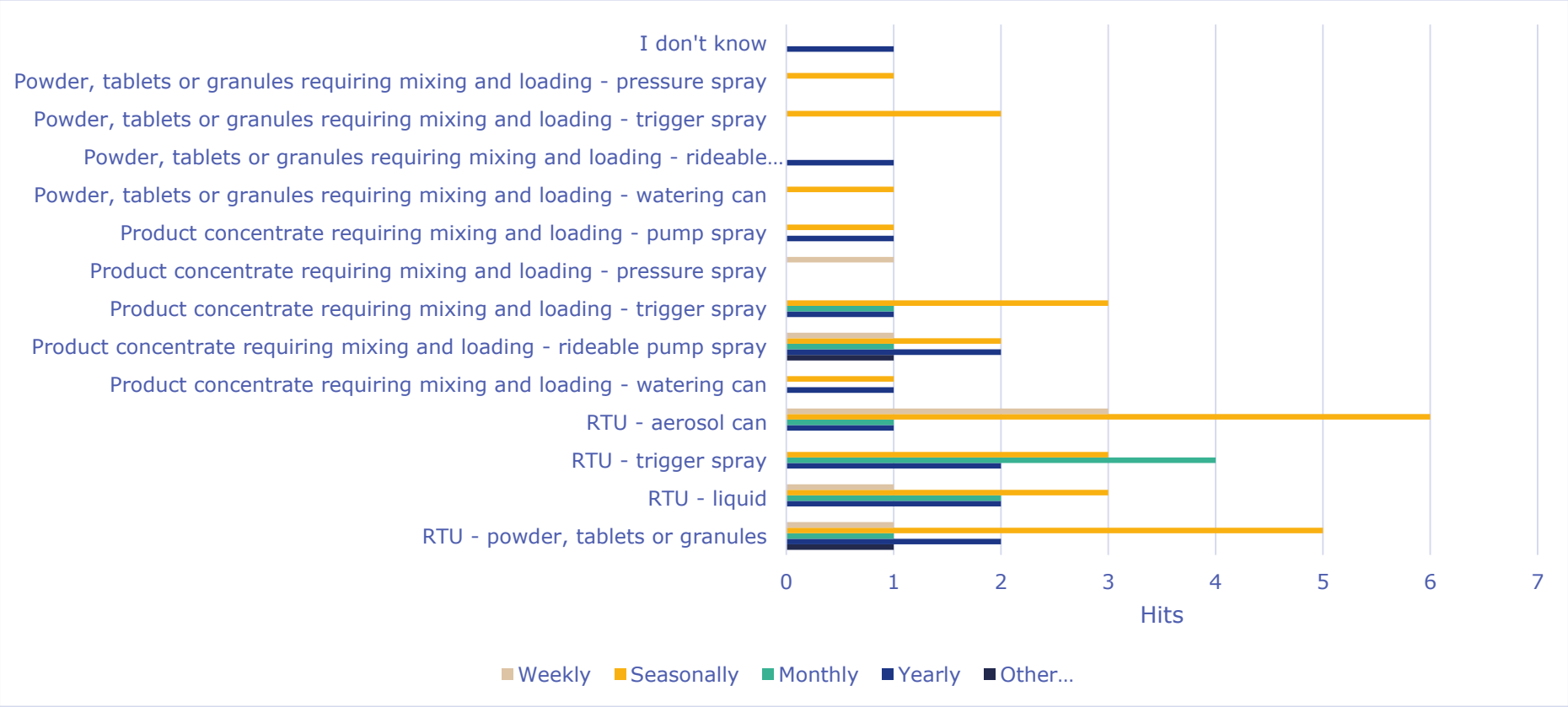
B55 – How often do you use that product?
Answered: 62



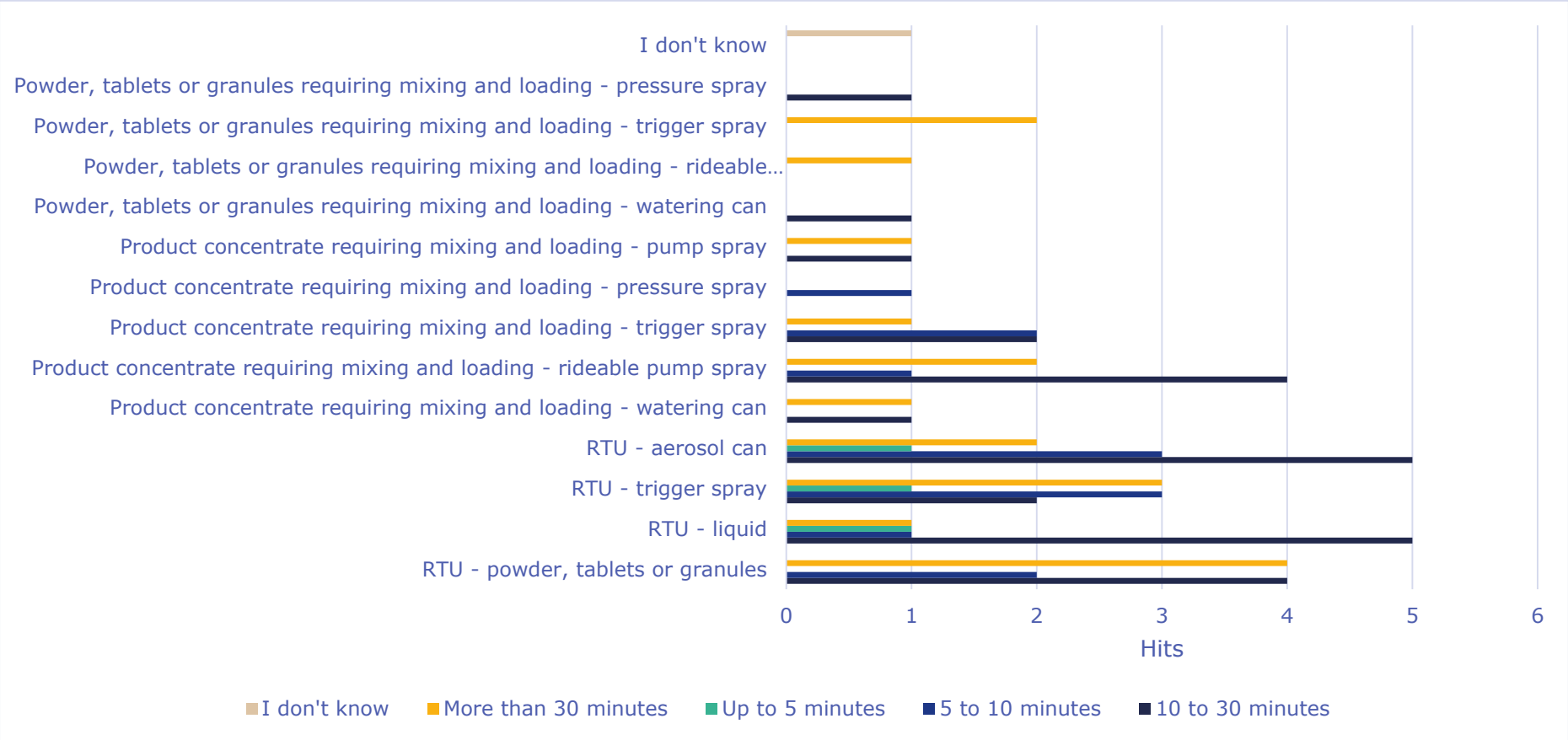
B56 – How long are you using the product each time you apply it?
Answered: 62



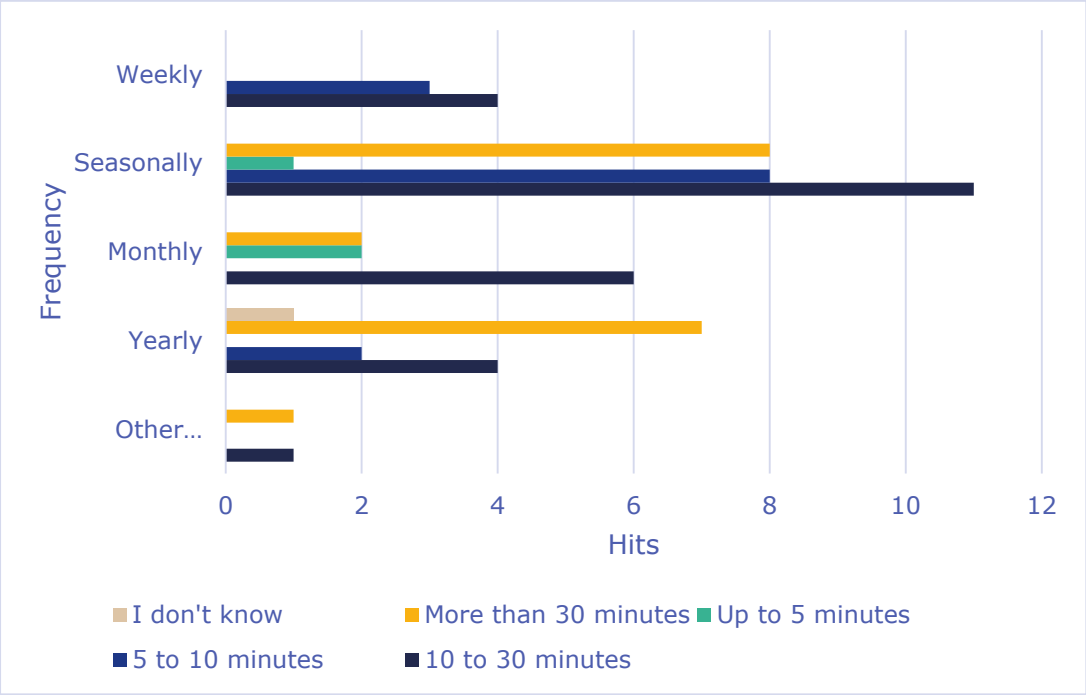
B57 – Frequency of use per application type



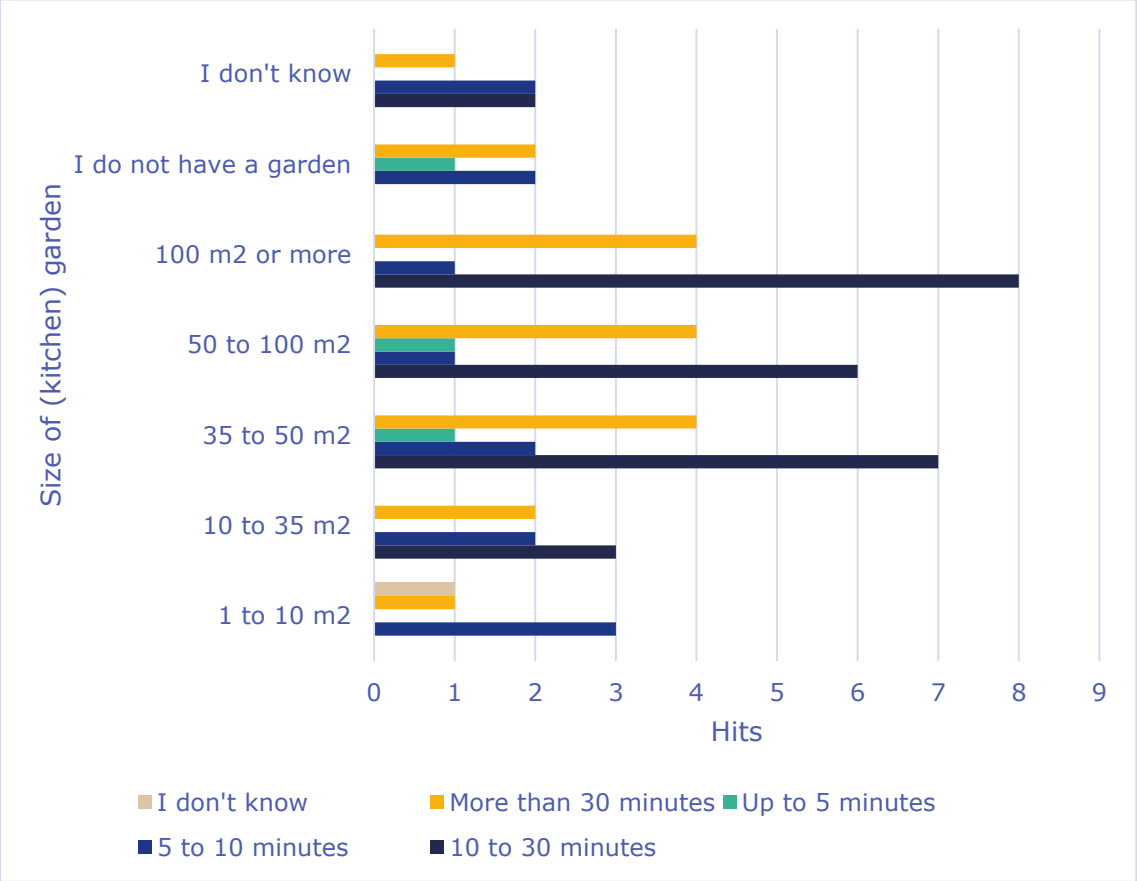
B58 – Duration of use per application type



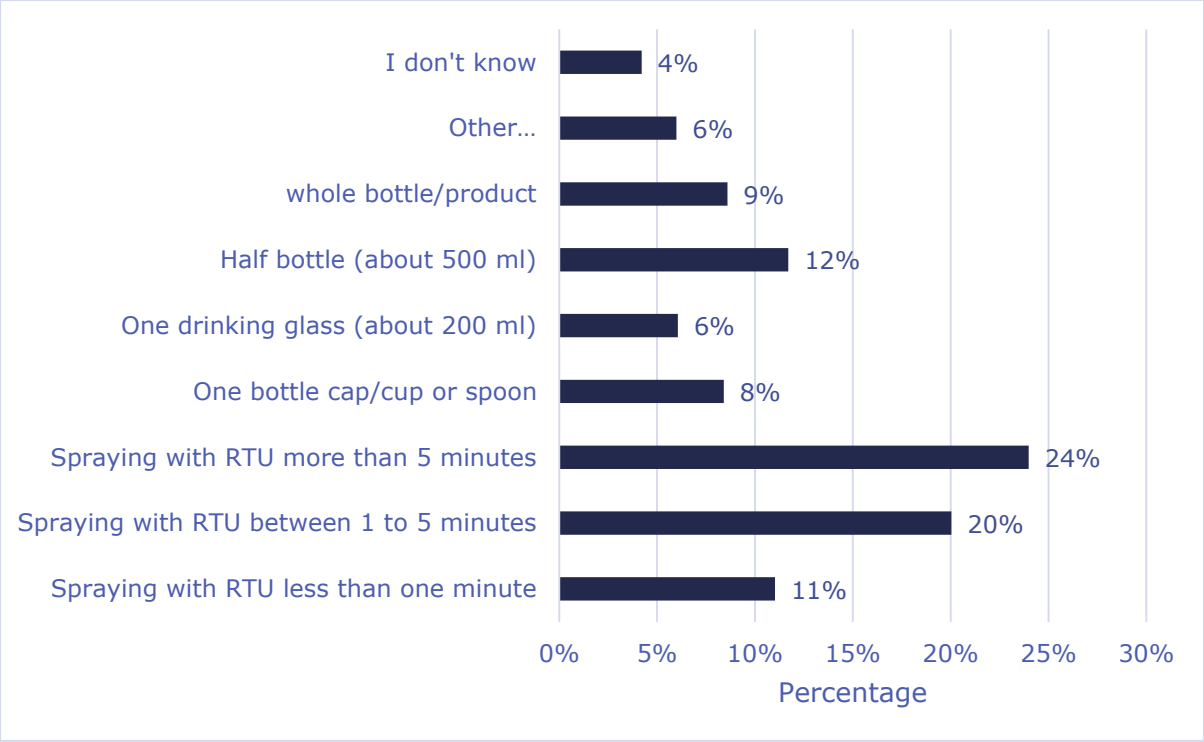
B59 – Frequency of use versus duration of use



B60 – Time of application versus size of (kitchen) garden



B61 – One a day of use, how much do you apply in case of a RTU product?
Answered: 62



B62 – Amount used per size of (kitchen) garden

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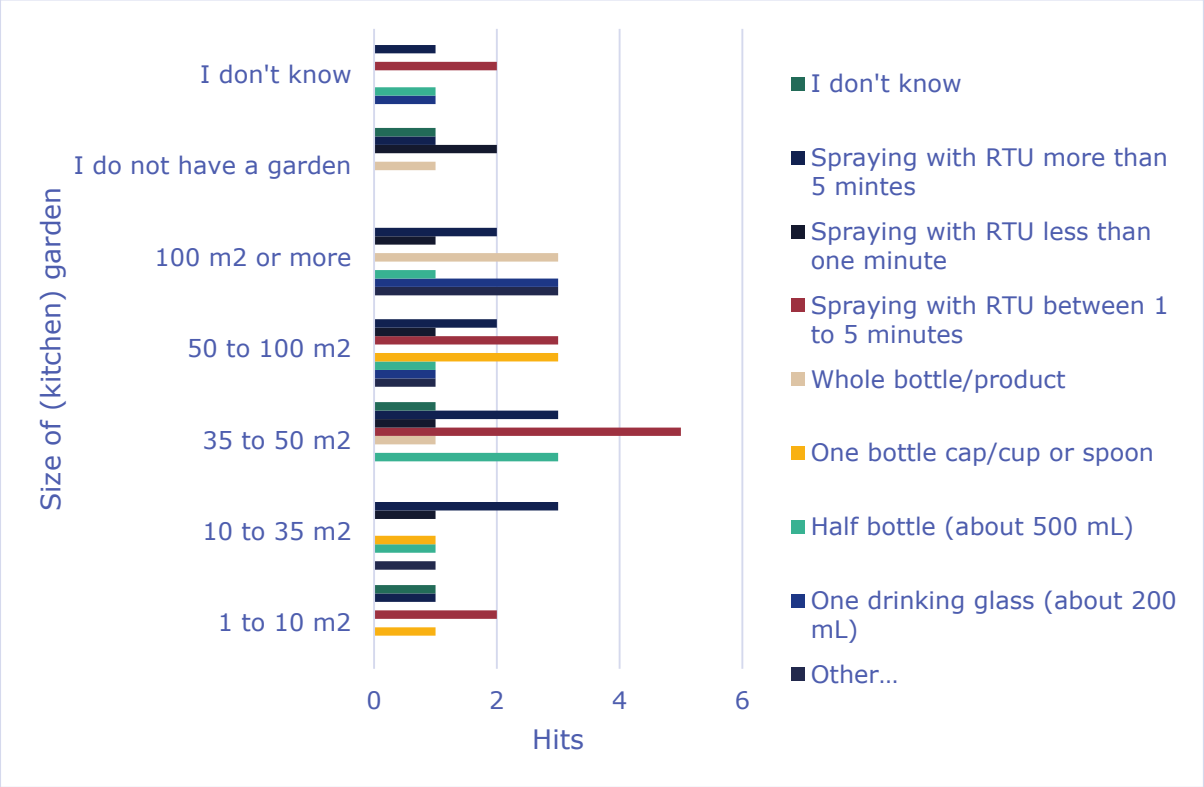
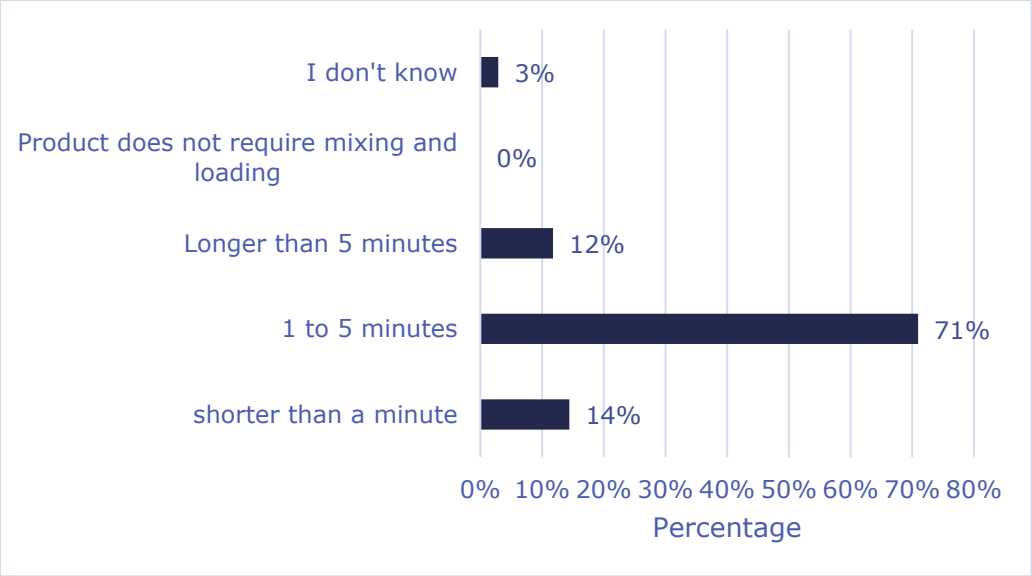


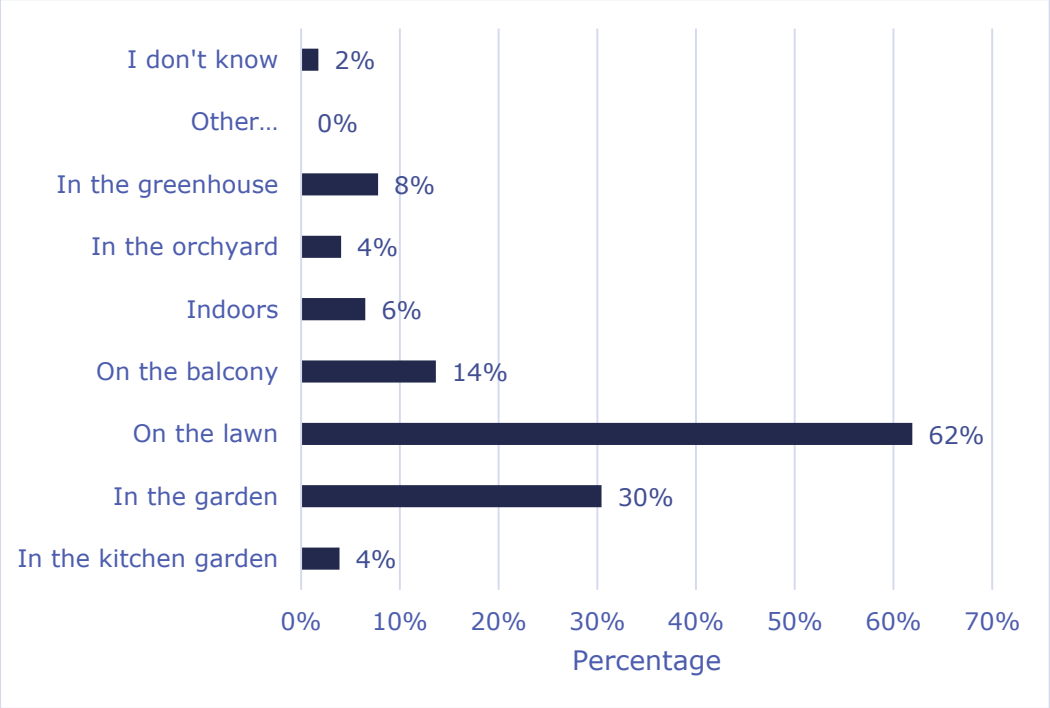
B63 – If the product requires mixing and loading, how much time does that consume?
Answered: 21



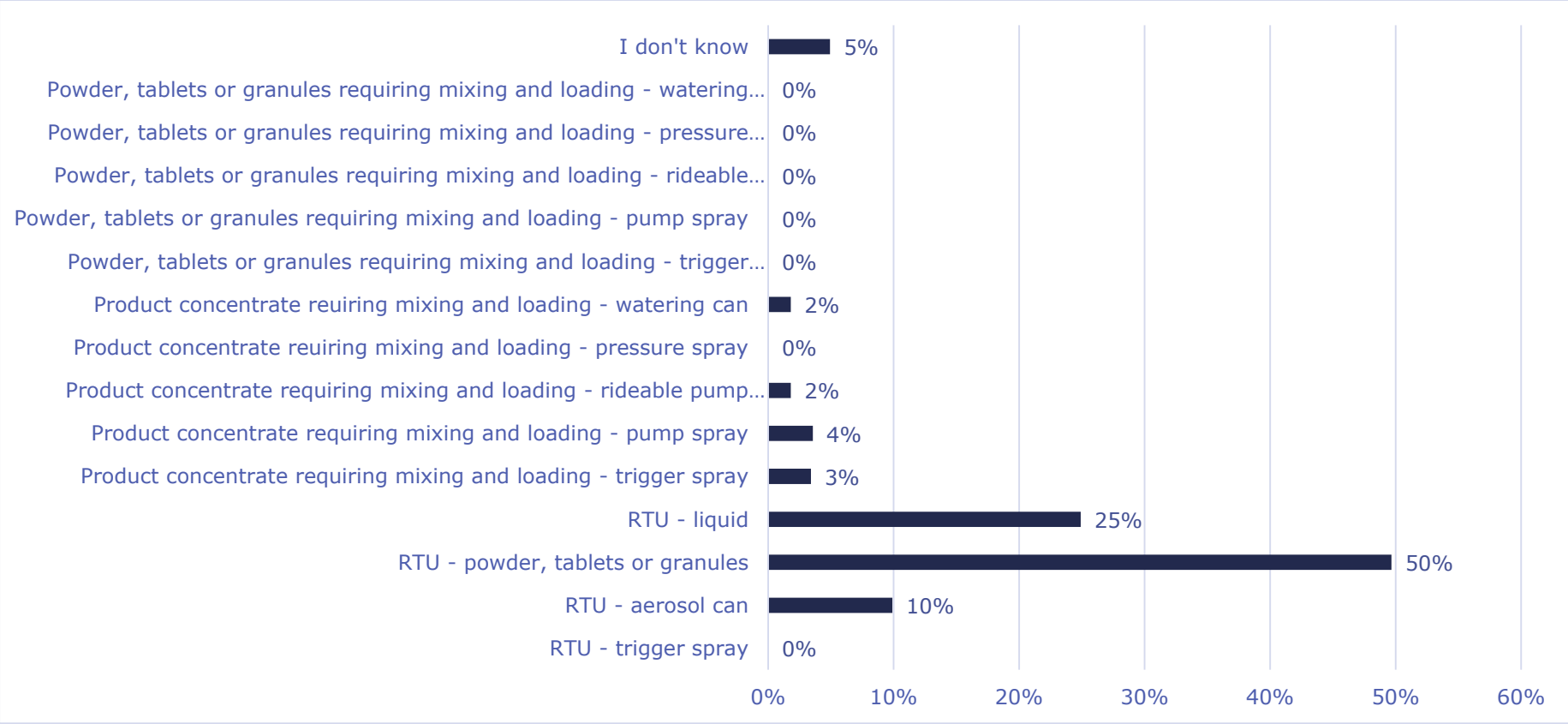
B64 – Do you wear any protective gear?
Answered: 62

7.7 Lawn treatment product

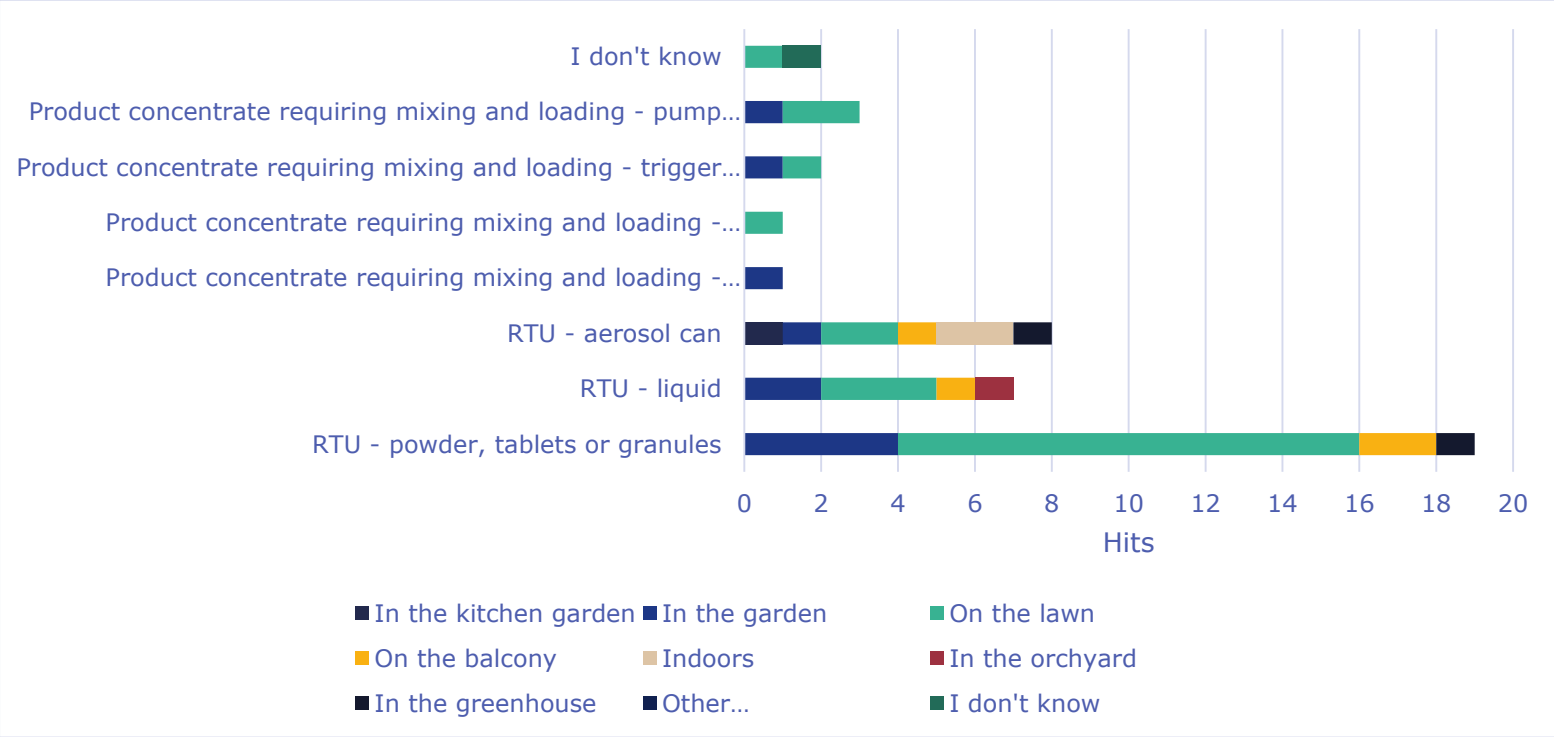
B65 – Can you specify where you apply lawn treatment product?
Answered: 34



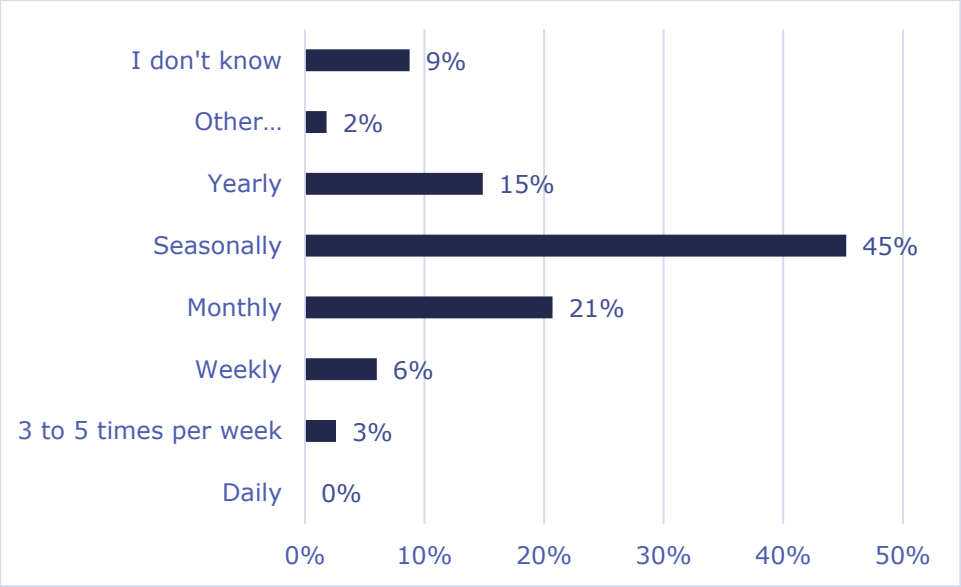
B66 – Can you specify what application type you use?
Answered: 34



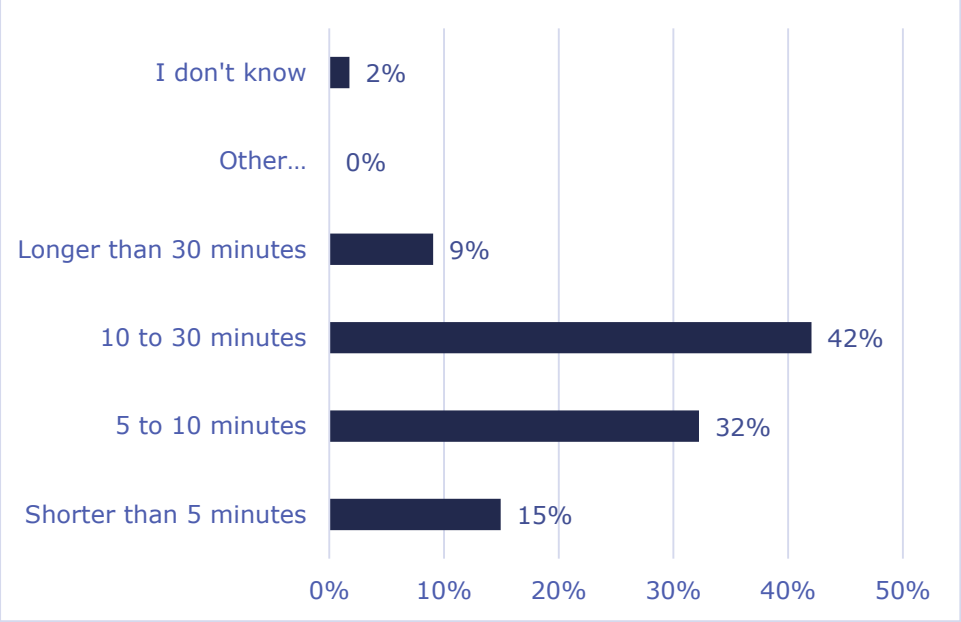
B67 – Location of use per application type



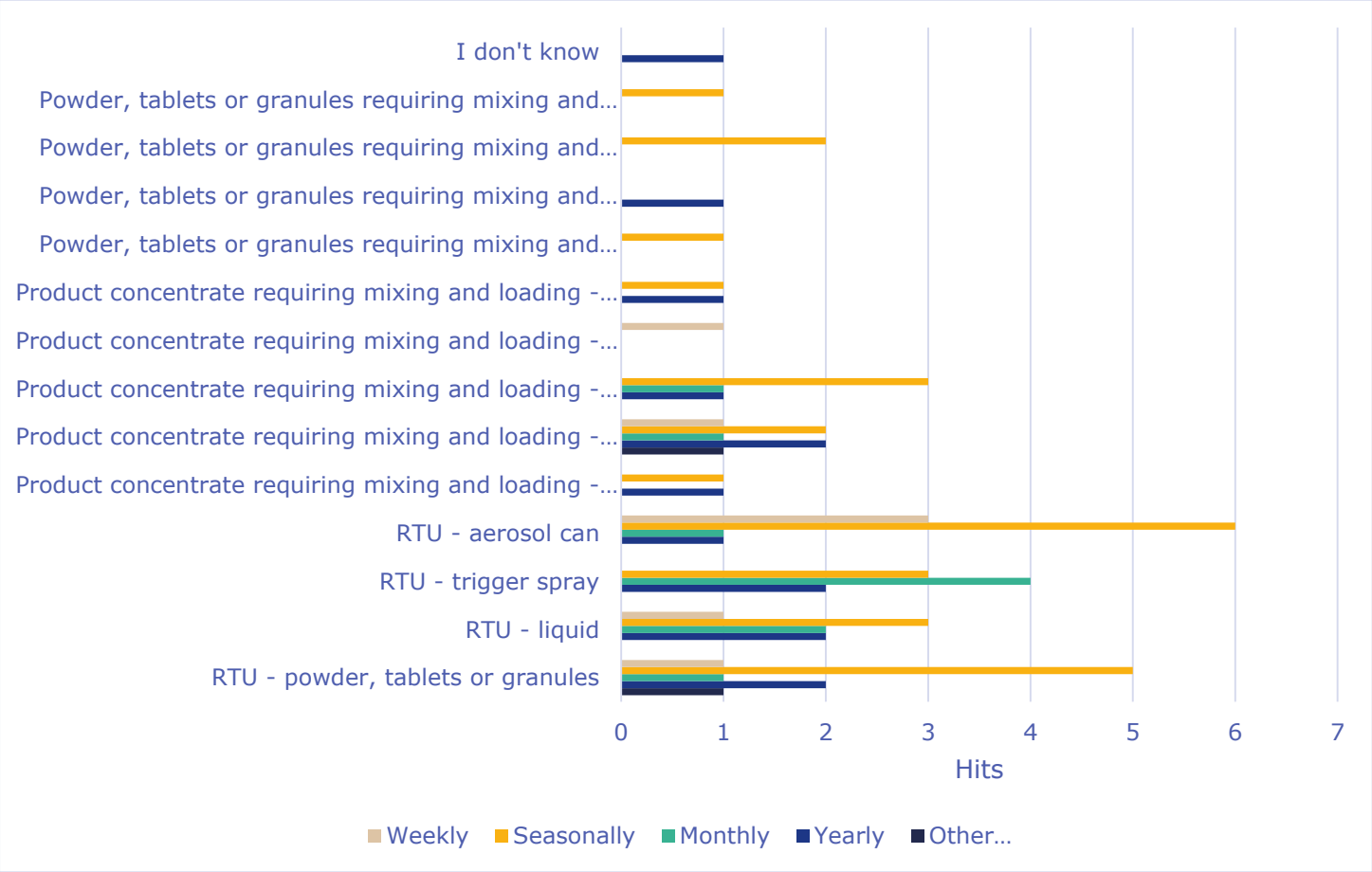
B68 – How often do you use that product?
Answered: 34



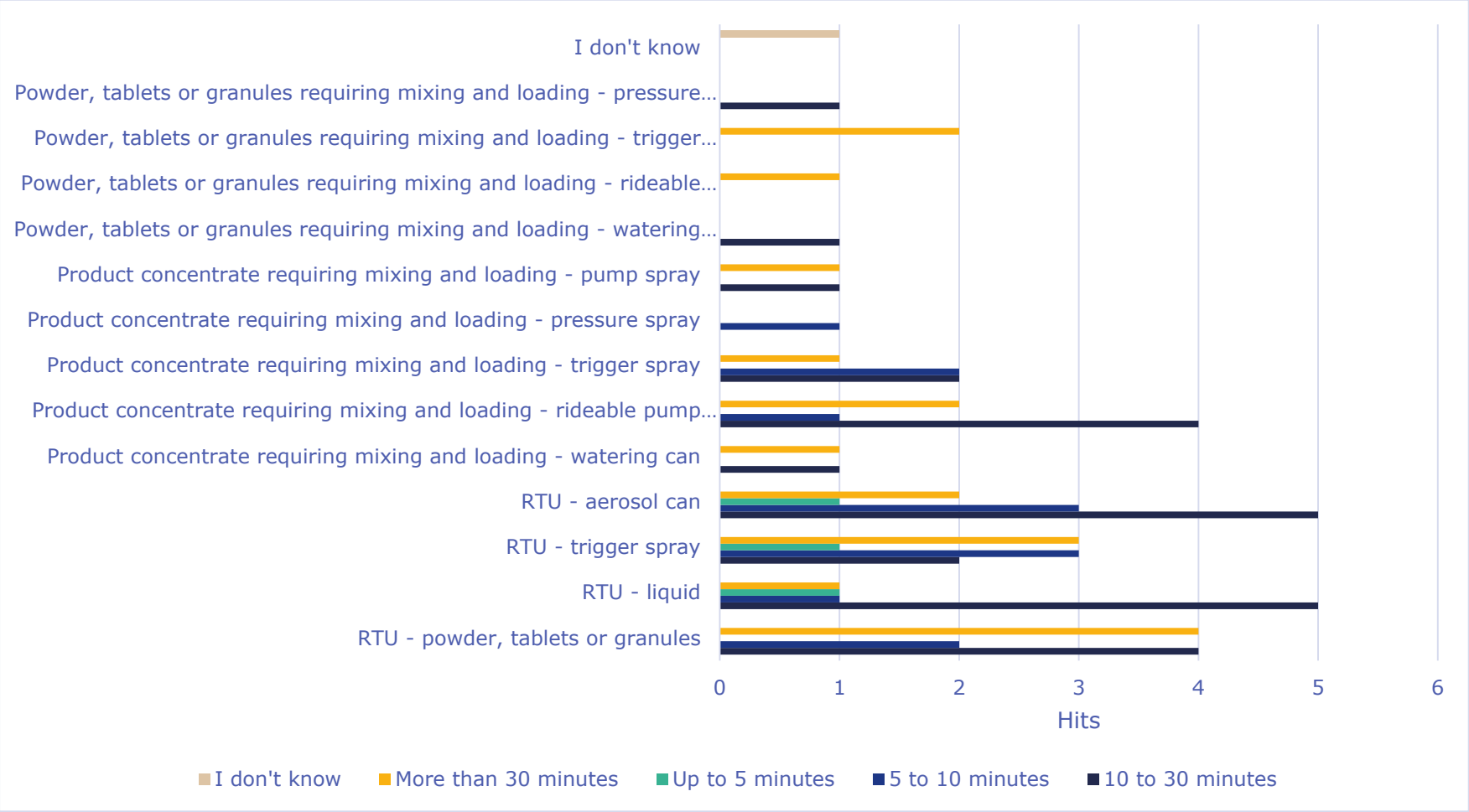
B69 – How long are you using the product each time you apply it?
Answered: 34



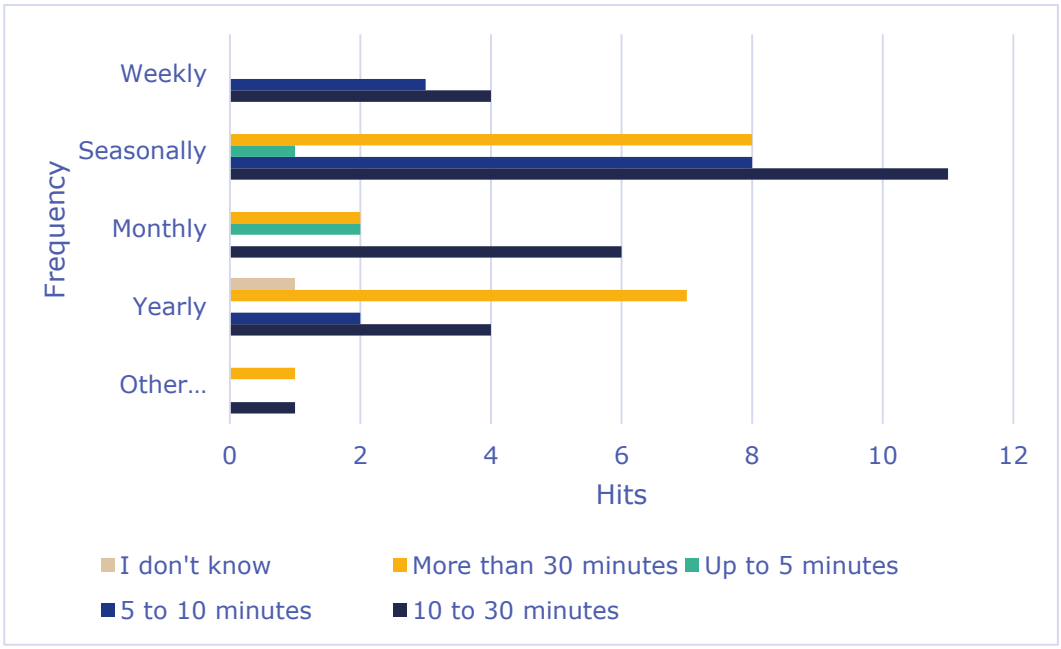
B70 – Frequency of use per application type



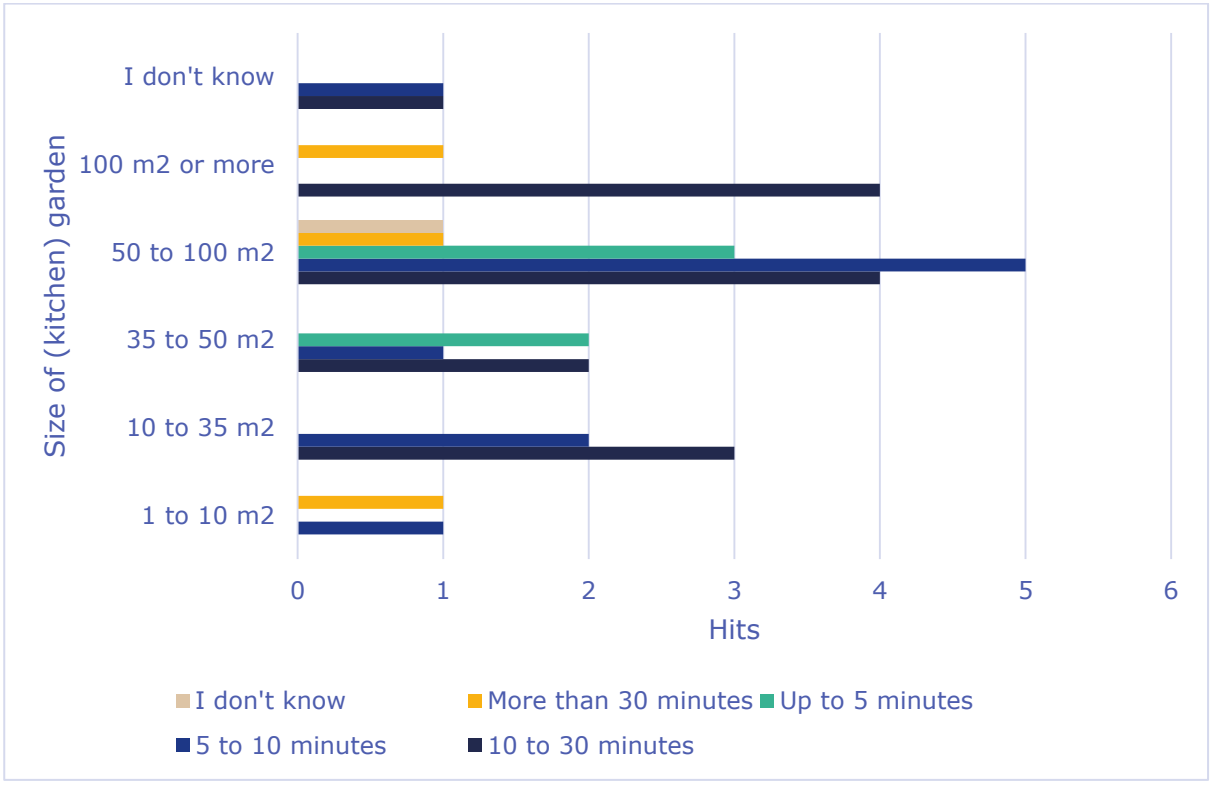
B71 – Duration of use per application type



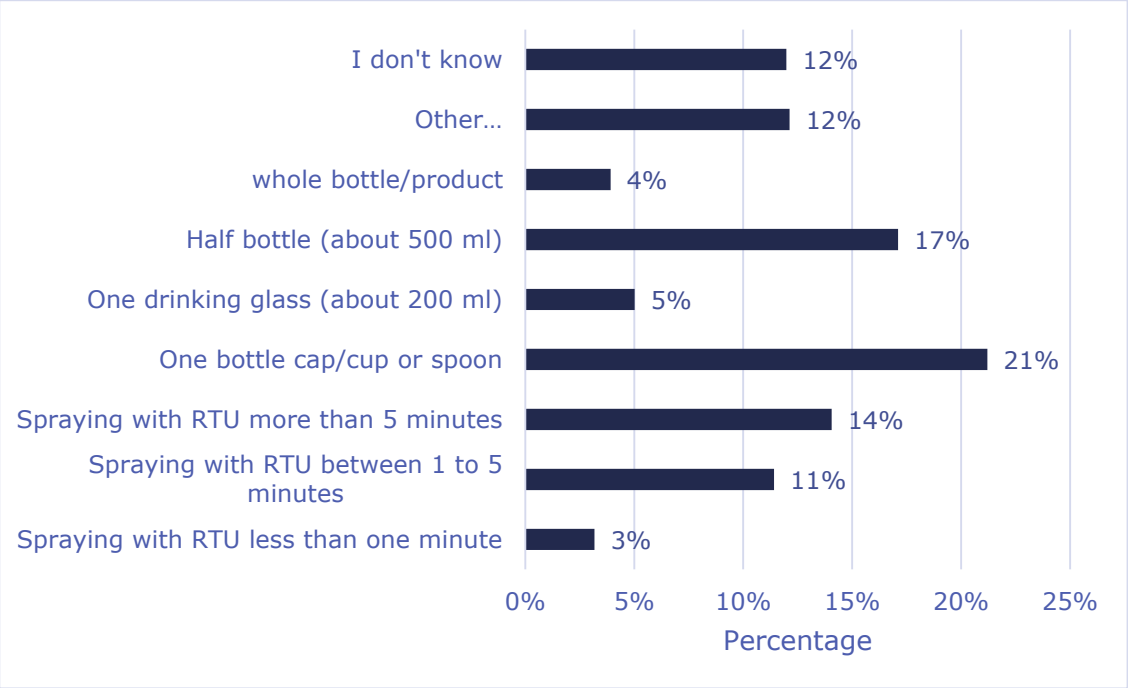
B72 – Frequency versus duration



B73 – Time of application versus size of (kitchen) garden

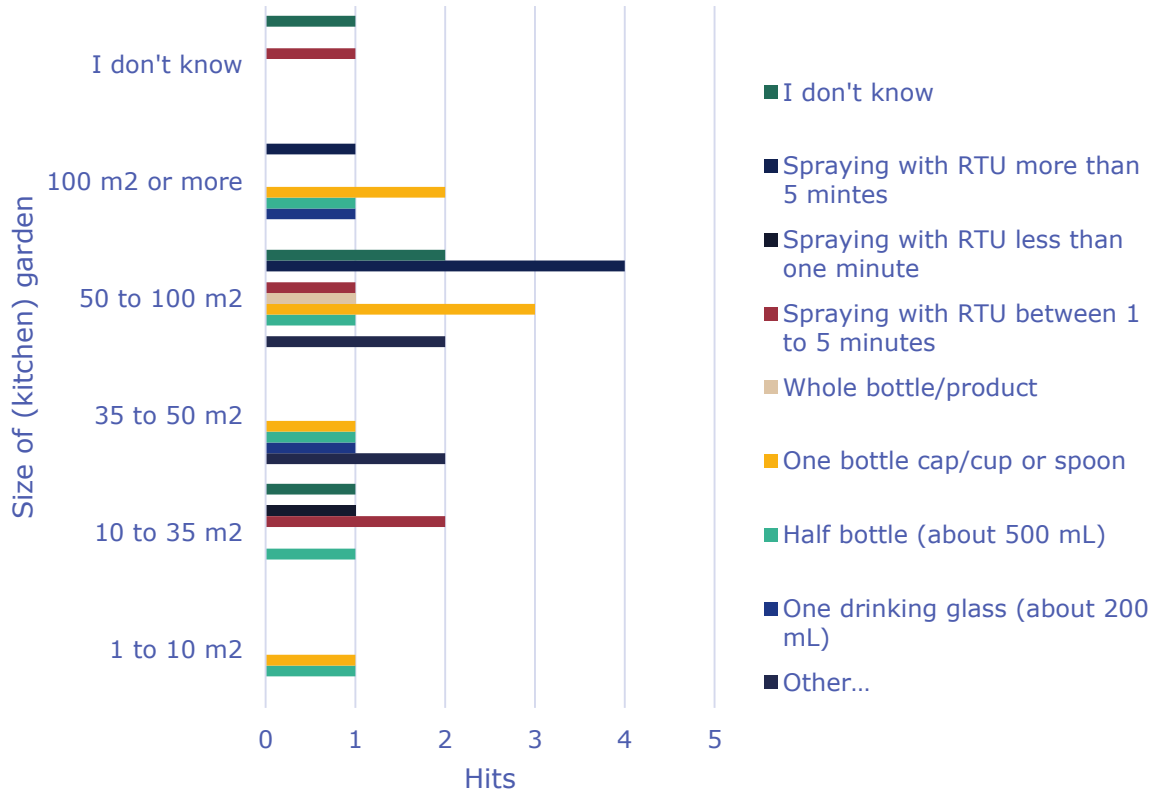


B74 – One a day of use, how much do you apply in case of a RTU product?
Answered: 34

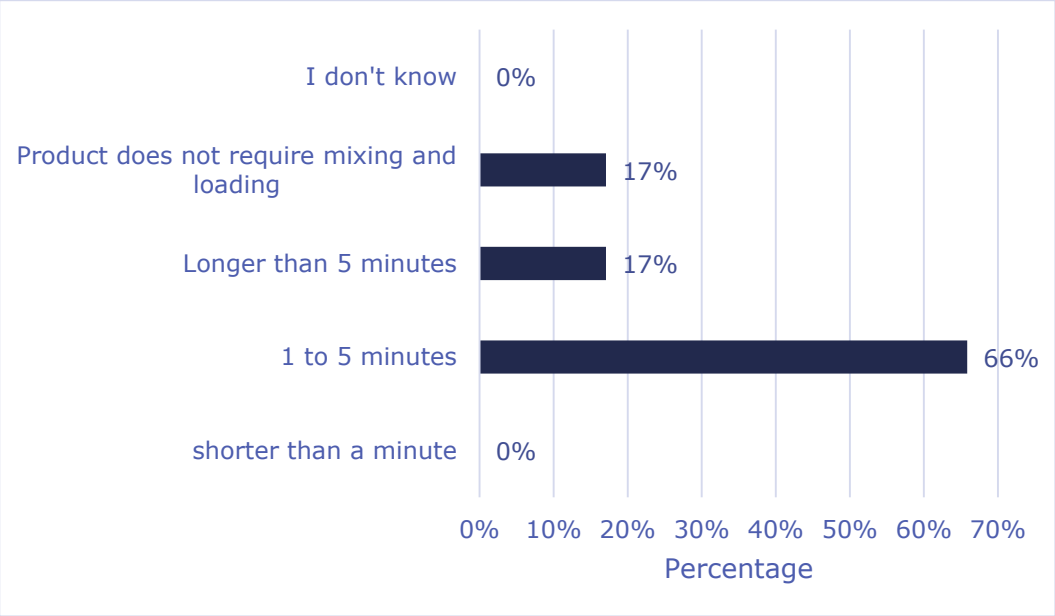


B75 – Amount used per size of (kitchen) garden

Data and methodologies non-professional PPPs exposure assessment



B76 – If the product requires mixing and loading, how much time does that consume?
Answered: 4



B77 – Do you wear any protective gear?
Answered: 34

Annex C – Authorities' Survey – Results (Greece - BPI)

Country - **Organisation/Authority**

In total fourteen (14) authorities have participated in the survey:

EU Member State	Organisation/Authority
Austria	AGES - Austrian Agence for Health and Food Safety
Belgium	Federal Public Service Health, Food Chain Safety and Environment / Service Plant protection and Fertilising Products
Denmark	Danish environmental protection agency
Finland	Finnish Safety and Chemicals Agency
Germany	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)*
Greece	Benaki Phytopathological Institute (BPI)
Ireland	Pesticide Registration and Controls Division, Department of Agriculture Food and the Marine
Italy	Ministry of Health
Lithuania	The State Plant Service under the Ministry of Agriculture
Netherlands	Dutch Board for the Authorisation of Plant Protection Products and Biocides - Ctgb
Norway	Norwegian Food Safety Authority; National Approvals Department
Slovenia	The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection
Spain	Ministry of Health**
Sweden	Swedish Chemical Agency (Kemikalieinspektionen)

* BVL is responsible for risk management and authorisation of PPP; the answers have been provided by BVL on the basis of the replies of the competent authorities for the risk assessment:

- Bundesinstitut für Risikobewertung (BfR) - Toxicology, Residues and respective analytical methods
- Umweltbundesamt (UBA) - Environmental Fate and behaviour, Ecotoxicology
- Julius Kühn-Institut - Bundesforschungsinstitut für Kulturpflanzen (JKI) - Efficacy, Honey bees
- Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) - Identity, Phys. chem. properties and respective analytical methods.

** Responses elaborated in collaboration with National Institute Occupational Safety and Health.

Chart C.0. Involvement of responders in the risk assessment of different chemicals/EU Regulations

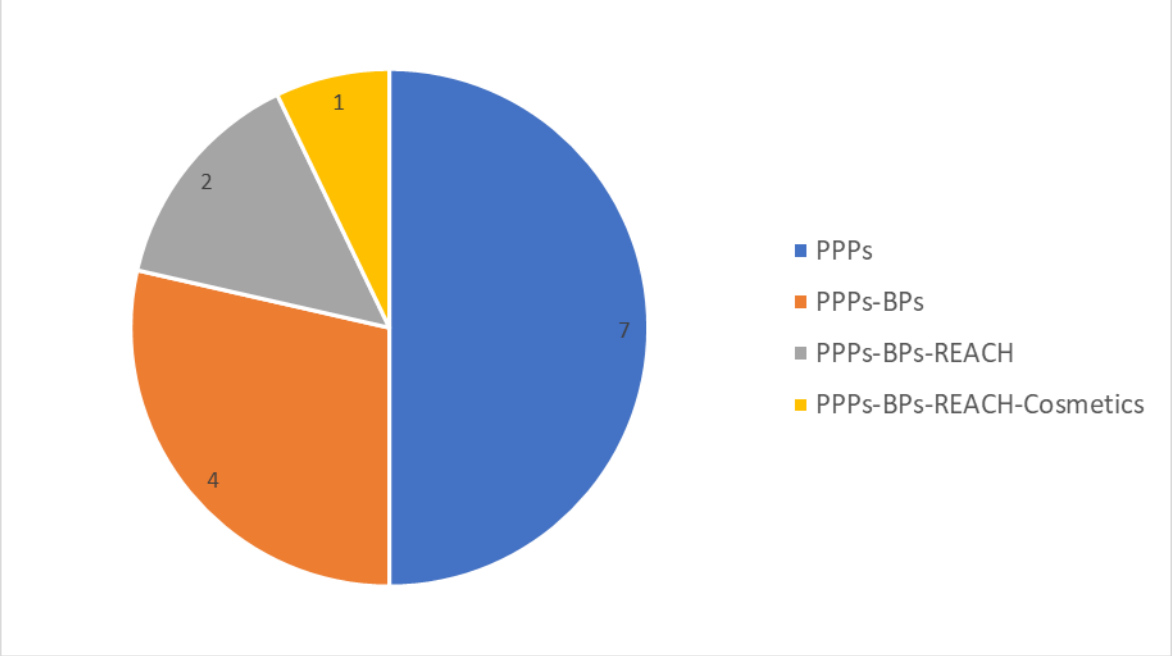


Chart C.1.0

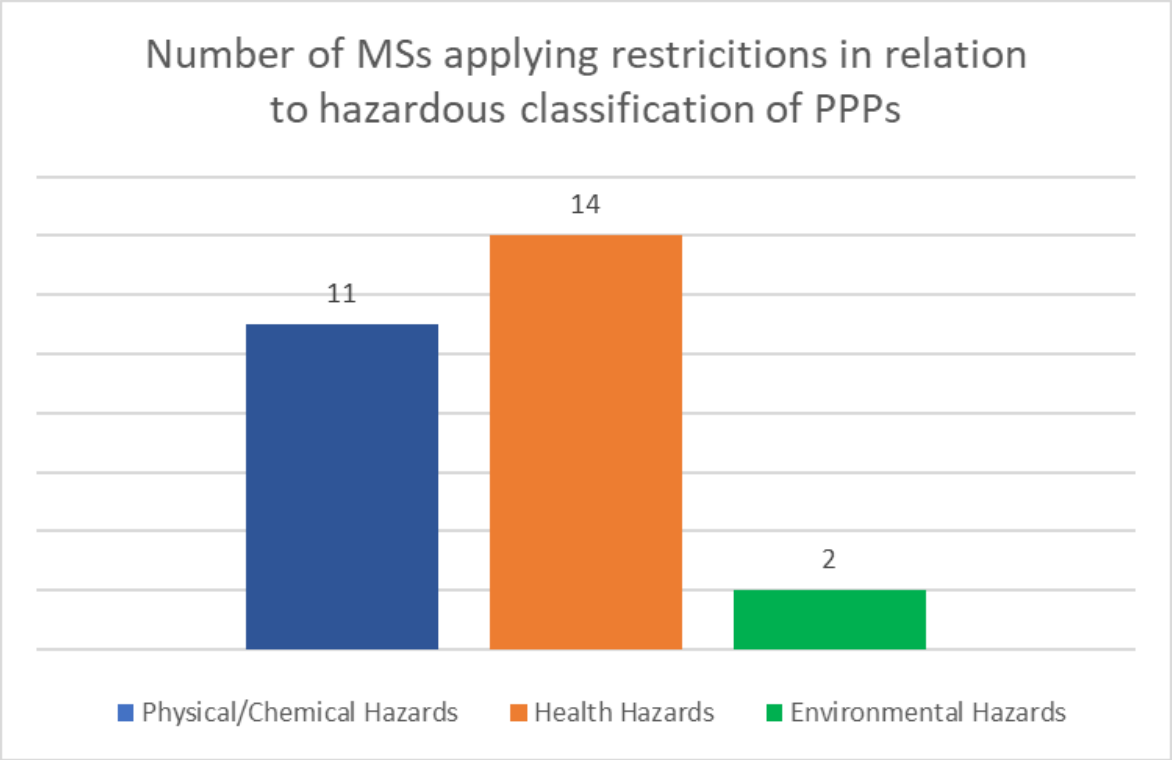


Chart C.1.1

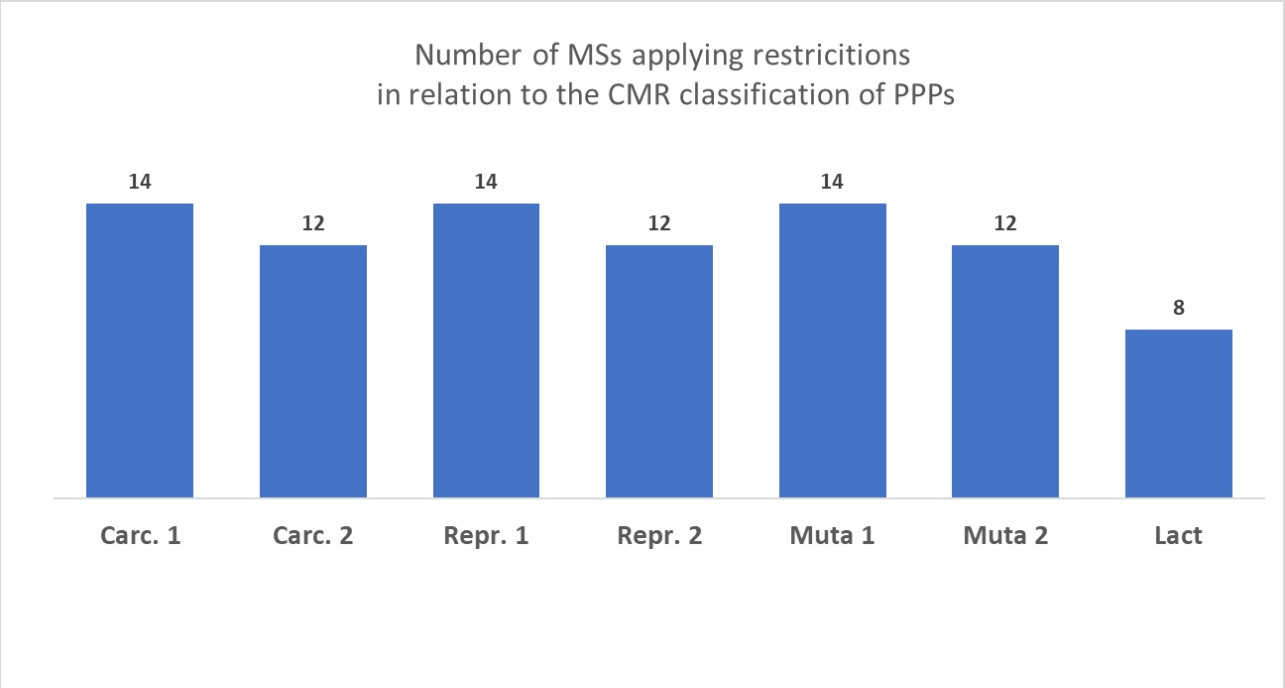


Chart C.1.2

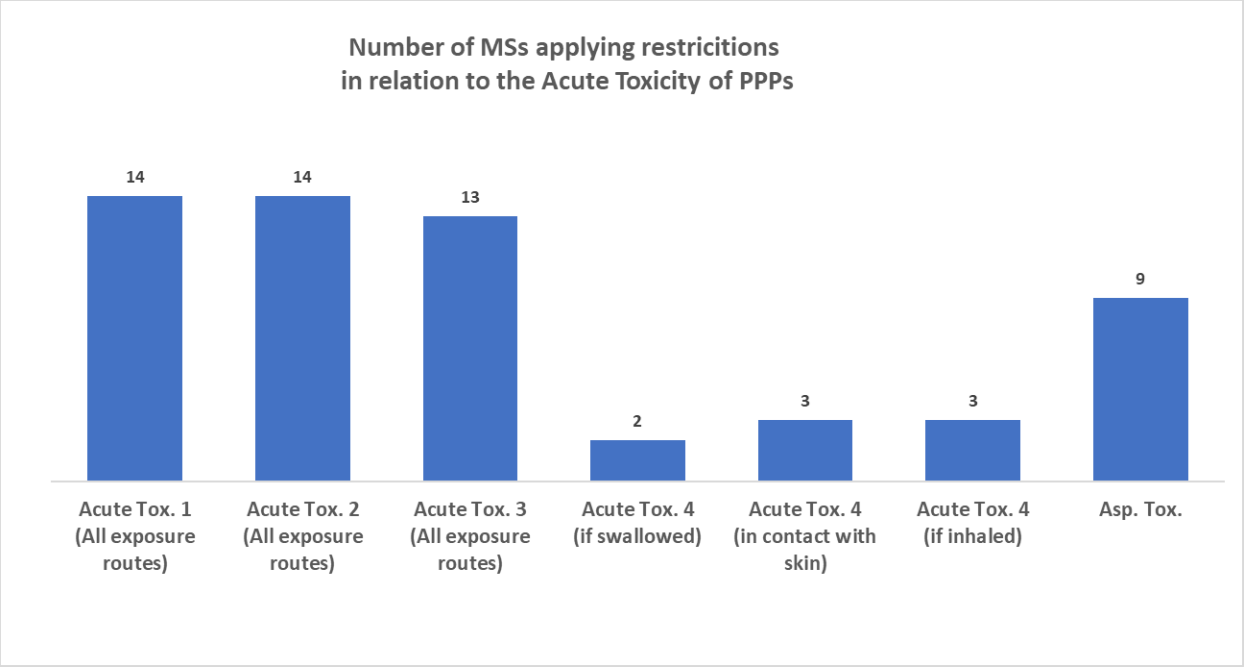


Chart **C.1.3**

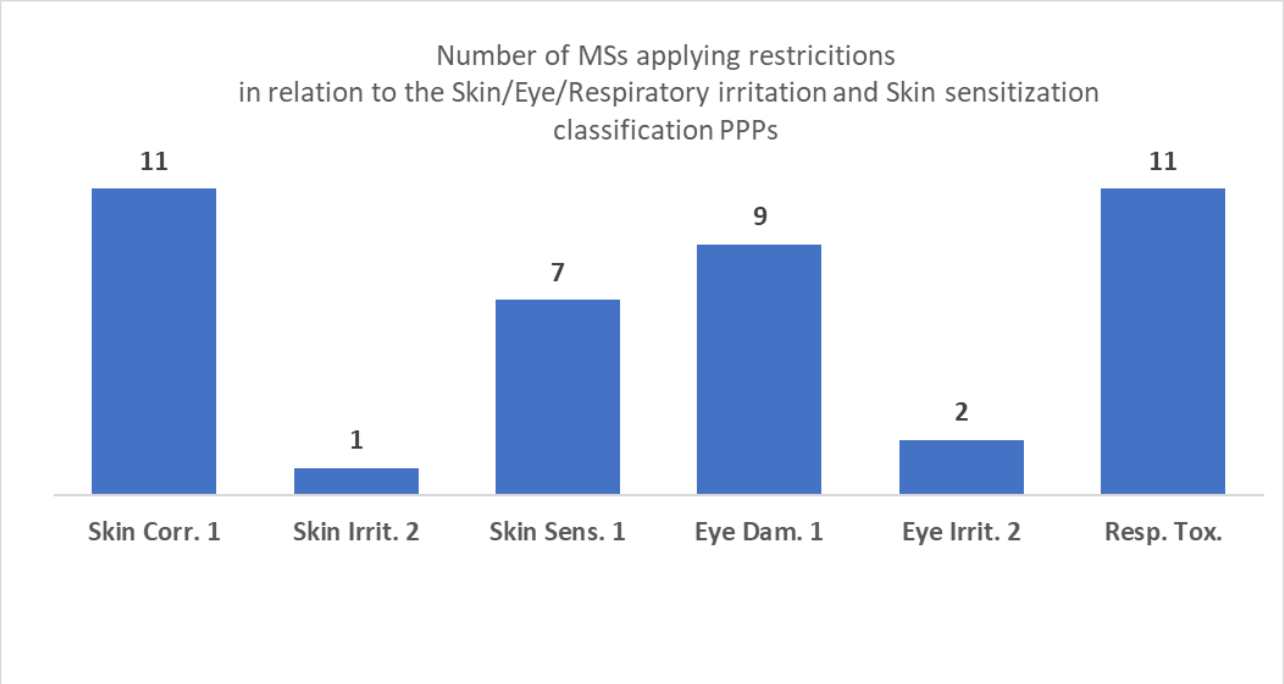


Chart C.1.4

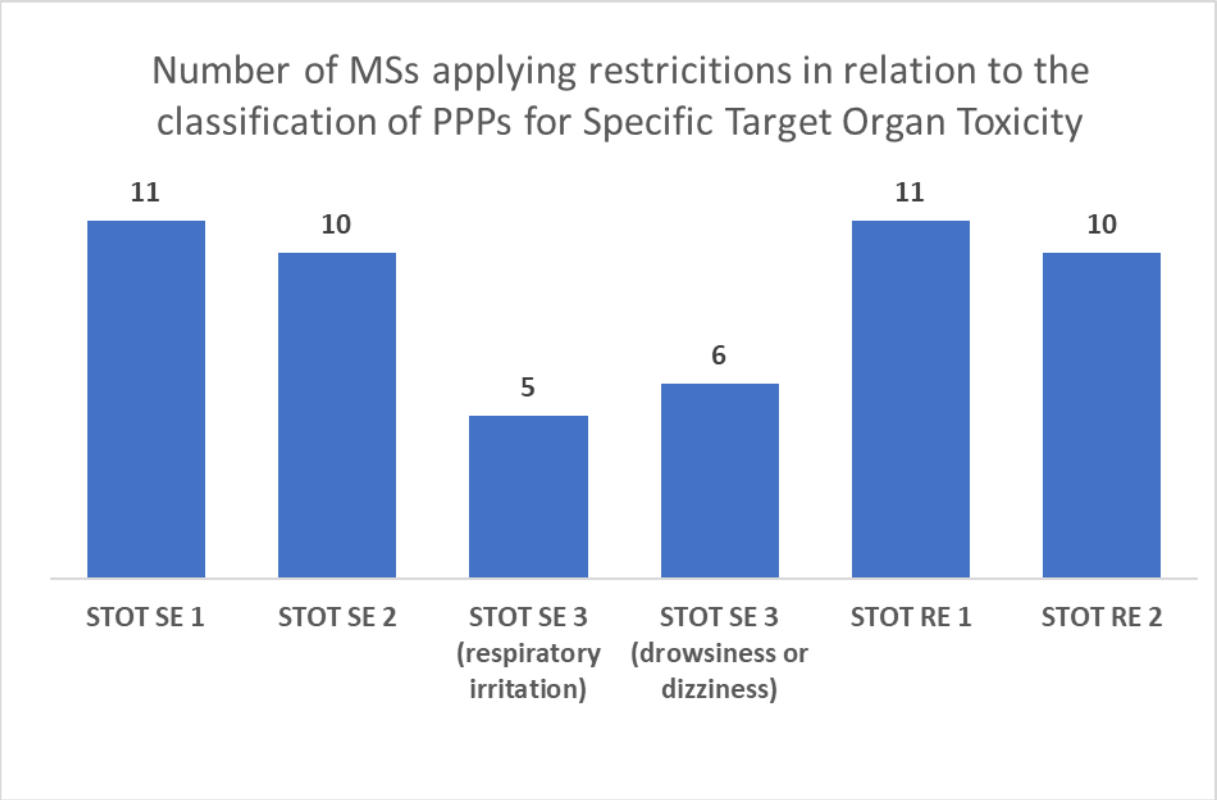


Chart C.1.5

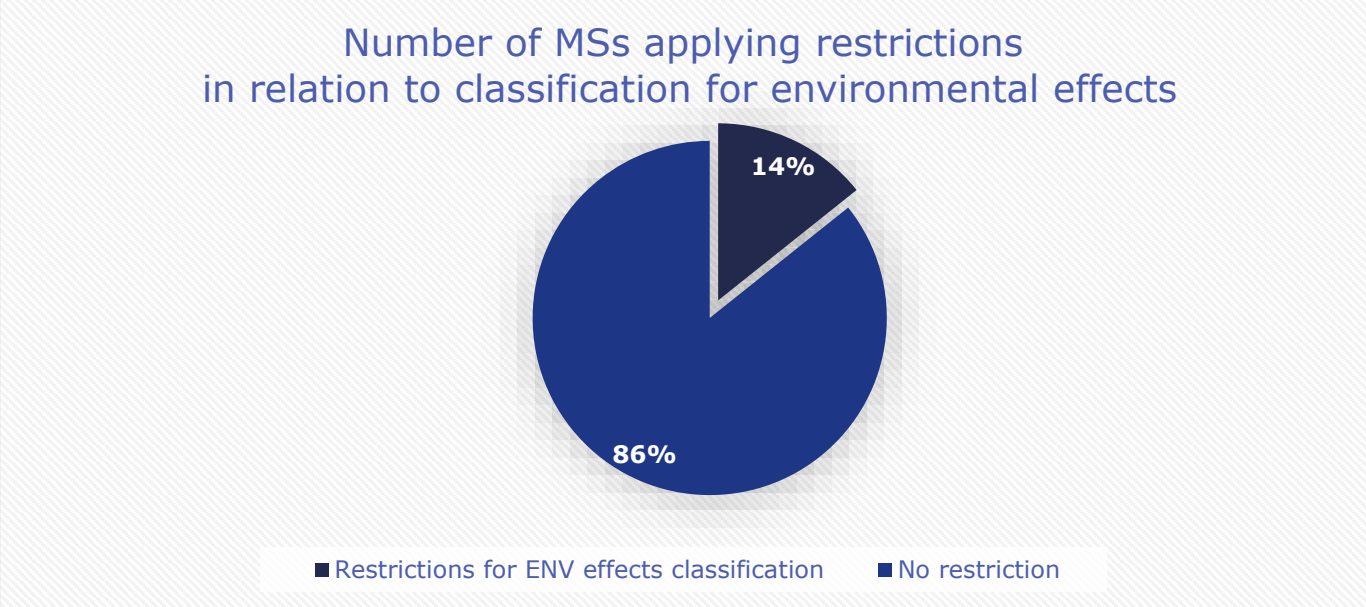


Chart C.1.6

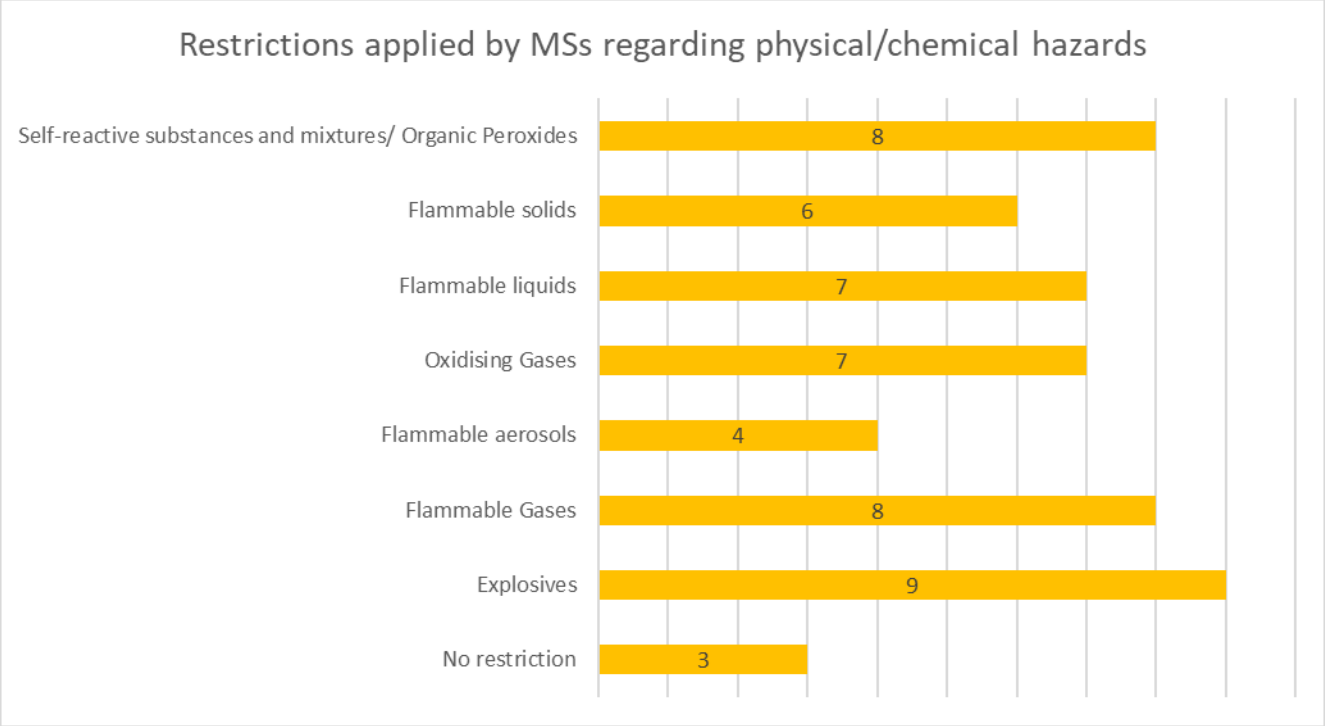


Chart C.2.1

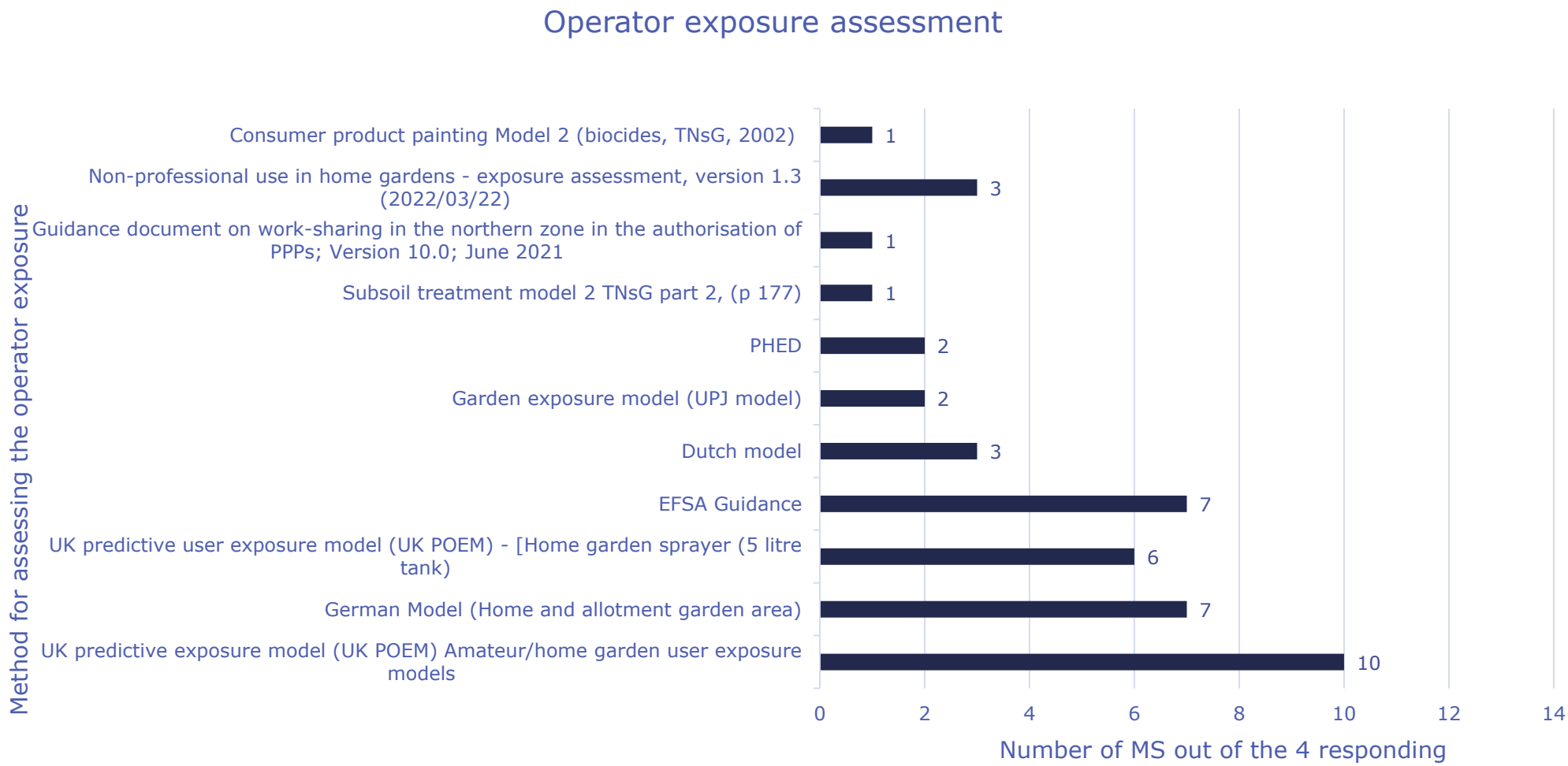


Chart C.2.2

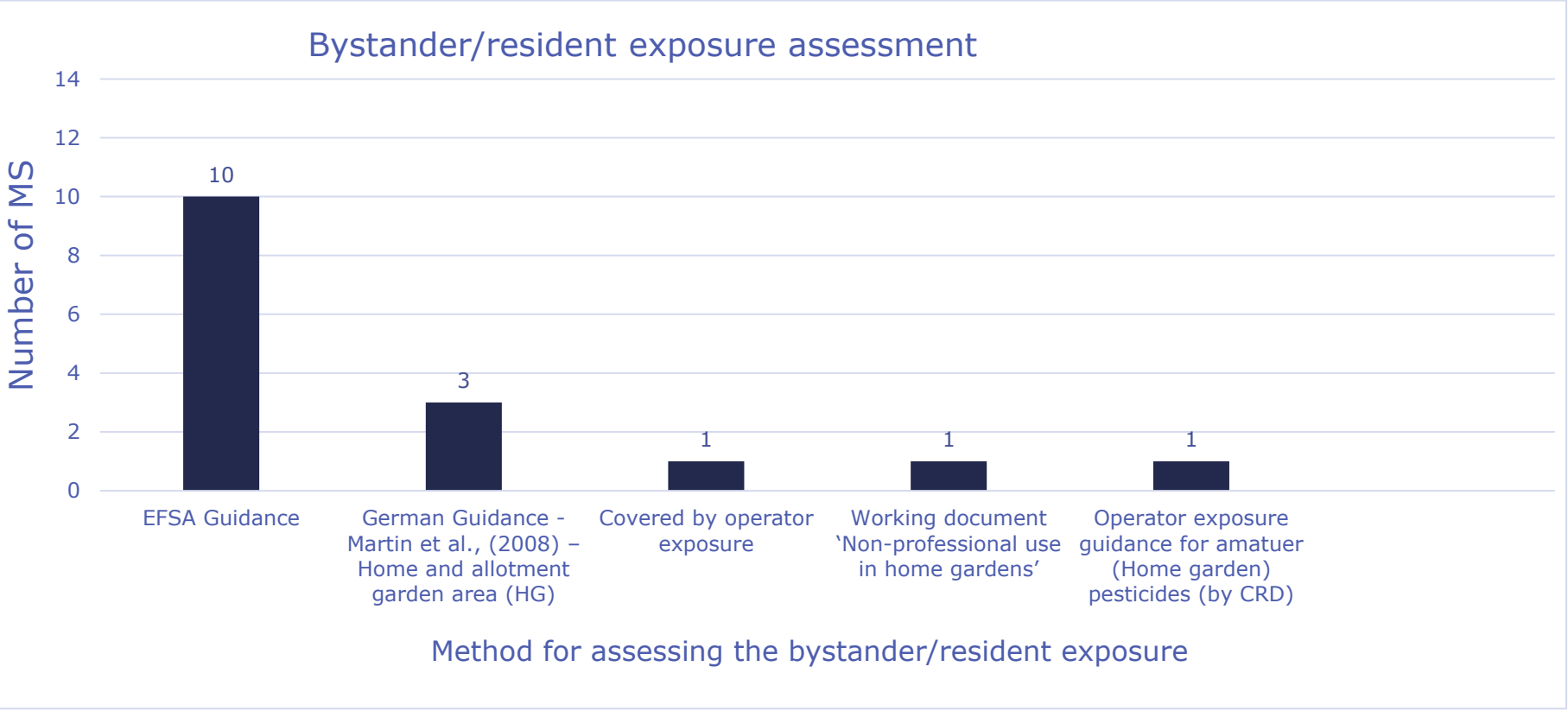


Chart C.3

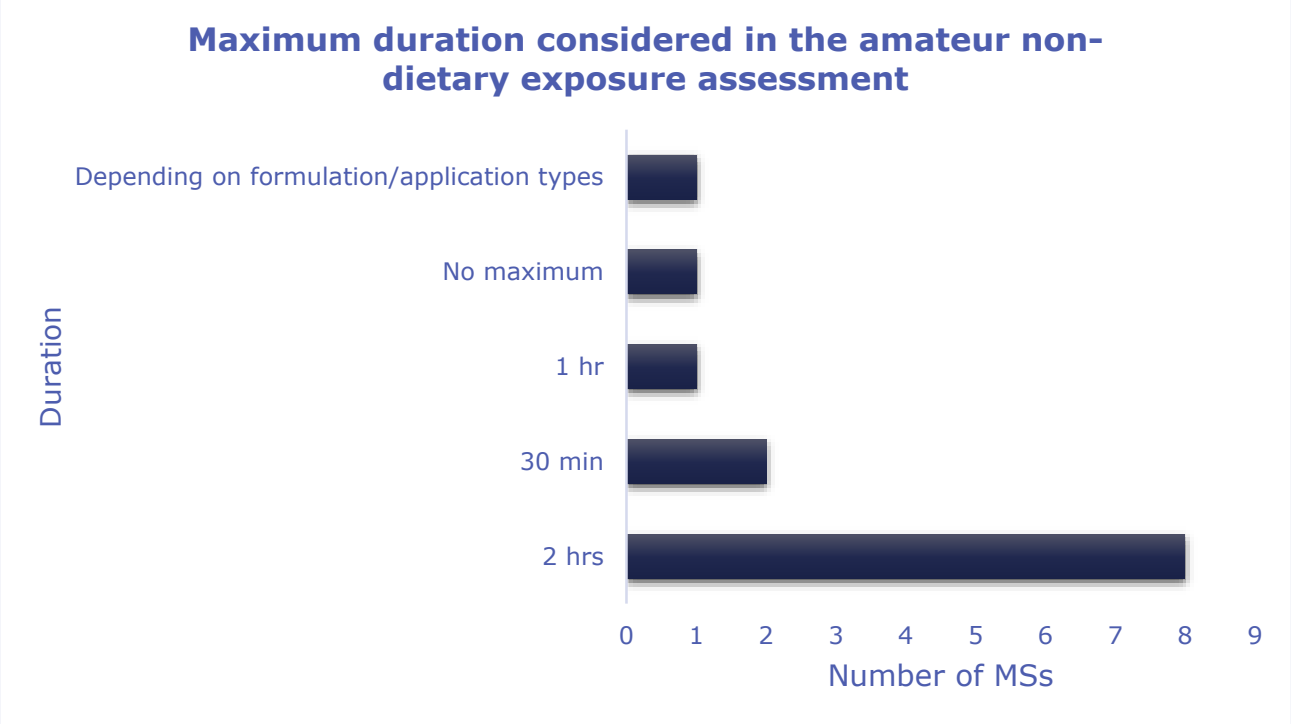


Chart C.4

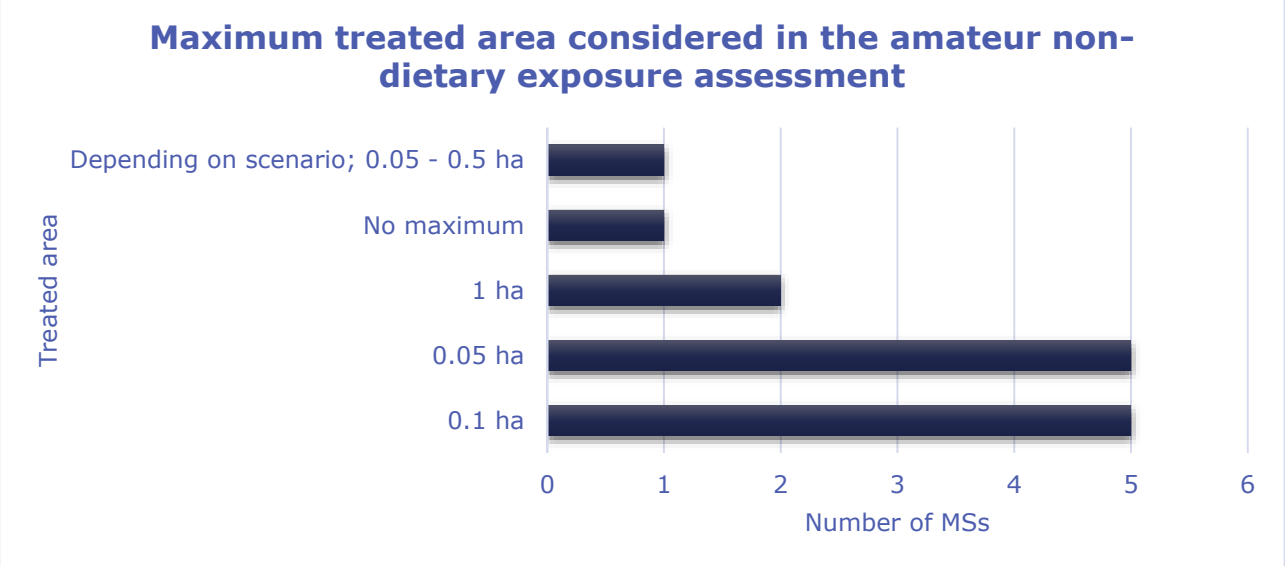


Chart C.5

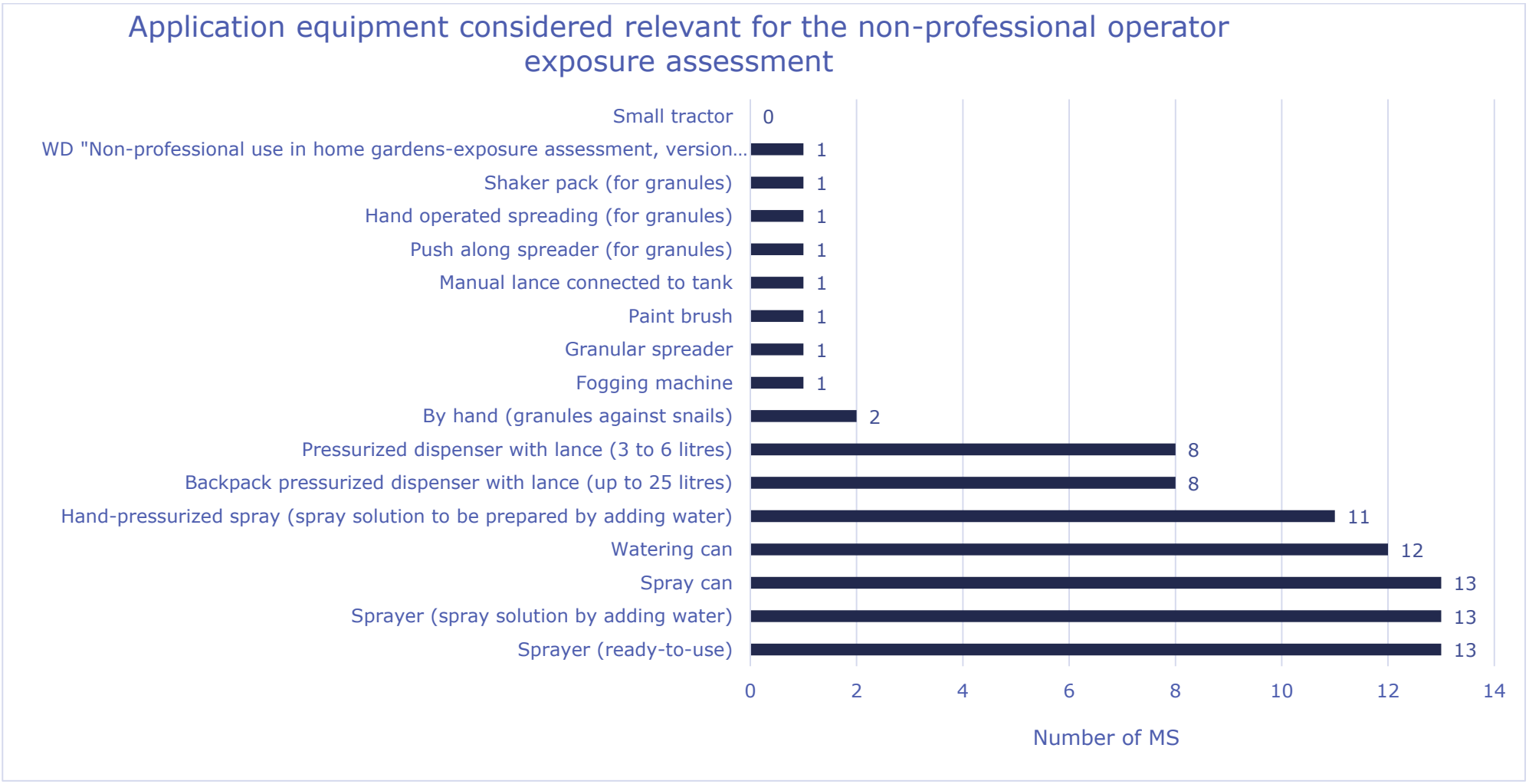
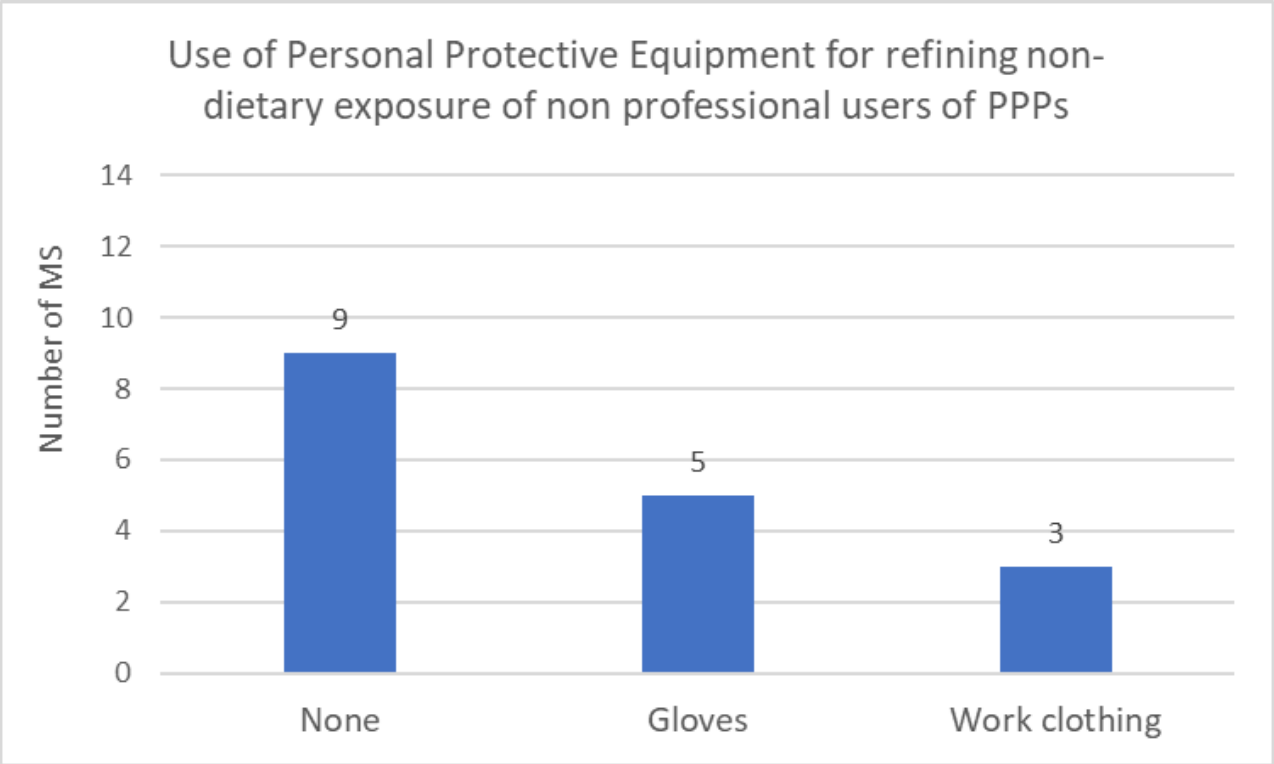


Chart C.6



Non-dietary exposure assessment: National requirements / National/Zonal Guidance Documents

Member State	Information provided
Austria	There is a national amateur-use guideline (in german), containing a list of prohibited classifications (CMR, corrosive, etc.) and some specialities for uses in Austria. For example, products classified for skin sensitization can be used for amateur uses, however, precautionary statement P280 should only contain gloves but not protective clothing, as this cannot be expected for amateur users. Instead, the statement "long-sleeved shirt, long trousers and sturdy shoes when applying the product" must be labelled.
Belgium	GUIDANCE FOR THE APPLICANT OF AN AUTHORISATION OF A PLANT PROTECTION PRODUCT, March 2020; *Annex 6: Instructions for the applicant of an authorisation for a product for non-professional users* *Annex 7: List of crops adapted for non-professional users* *Annex 8: List of pests adapted for non-professional users*

	Annex 9: Check-list « Conformity and precision of packaging and measuring device for products for non-professional use submitted for authorisation in Belgium »
Denmark	Framework for the Assessment of Plant Protection Products, Department of Pesticides and Biocides Danish Environmental Protection Agency Reference to the *Northern Zone Guidance Document* [Guidance document on work-sharing in the northern zone in the authorization of plant protection products (Version 10.0; June 2021)].
Germany	izSC Item 07a Working Document Non professional use in home gardens Version 1.3 2022-03-22-1
Greece	Specific rules are in place regarding the restrictions applied regarding packaging and hazard classification and the specific parameters considered relevant for the non-professional use of PPPs such the treated area and the work rate [***ΥΑ 9519/105300/21.08.2014.*** *Χορήγηση άδειας διάθεσης στην αγορά σε σκευάσματα φυτοπροστατευτικών προϊόντων για ερασιτεχνική χρήση* ***(ΦΕΚ 2331 Β΄29.08.2014)***]. Addional instructions are provided regarding the exposure assessment models to be used in the National Requirements [Documents available in Greek].
Italy	The Italian requirements on PPPs for non-professional use and the Italian approach to exposure assessment are included in specific documents available in Italian, i.e. - *Prima revisione della Linea guida nazionale "Modelli di valutazione dell'esposizione e dei rischi per la salute, l'ambiente e gli organismi non bersaglio connessi all'uso non professionale dei prodotti fitosanitari"*. (Decree 25 July 2022, guideline for exposure assessment_non-professional use) - *LINEA GUIDA; VALUTAZIONE DELL'ESPOSIZIONE E DEI RISCHI PER LA SALUTE, L'AMBIENTE E GLI ORGANISMI NON BERSAGLIO CONNESSI ALL'USO NON PROFESSIONALE DEI PRODOTTI FITOSANITARI* Regarding the Italian Decree of 20 November 2021-requirements of PPP for non professional use, a summary is also available in English where an assessment approach for exposure to the environment and non-target organisms is also presented [*Summary of requirements for plant protection products intended for non-professional uses in Italian law - - DM n 33/2018 as modified by DM 20 Novembre 2022*]
Spain	Specific guidance/evaluation criteria are in place [criterioexpo.pdf (sanidad.gob.es); document available in Spanish] *Worker exposure assessment:* • *Insecticide/fungicide:* *ReadyToUse: TC= 5000 cm²/h (with workwear) and T= 2h* *Knapsack: TC= 5000 cm²/h (with workwear) and T=8h* • *Herbicide: TC= 1400 cm²/h (with workwear) and T= 2h*